

Ex. 1,
State Court
Complaint
with Exhibits

STATE OF MICHIGAN
IN THE 30TH CIRCUIT COURT FOR THE COUNTY OF INGHAM

VIRIDIS LABORATORIES, LLC,
a Michigan limited liability company, and
VIRIDIS NORTH, LLC,
a Michigan limited liability company,

Plaintiffs,

v.

JULIE KLUYTMAN, an individual, DESMOND
MITCHELL, an individual, ALLYSON CHIRIO, an
individual, and CLAIRE PATTERSON, an individual,

Defendants.

Case No. 22-**0119**-CZ

Hon. **JUDGE WANDA M. STOKES**

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VERIFIED COMPLAINT

*There is no other pending or resolved civil action between these parties arising
out of the same transaction or occurrence as alleged in this Complaint.*

Plaintiffs Viridis Laboratories, LLC and Viridis North, LLC (collectively “Plaintiffs”), by and through their attorneys, Foster, Swift, Collins & Smith, P.C. and Honigman, LLP, for their Complaint against Defendants Desmond Mitchell, Julie Kluytman, Allyson Chirio, and Claire Patterson state as follows:

INTRODUCTION

1. On November 17, 2021, the Michigan Marijuana Regulatory Agency (the “MRA”) commenced the largest recall of cannabis products in Michigan’s (and the legal and regulated cannabis industry’s) history (the “Recall”). The Recall covered between 60 to 70% of the cannabis industry’s existing on-the-shelf legal products or products that were on their way to shelves for recreational use. This equated to approximately \$229 million in commerce disturbed because of the MRA’s decision. All of the cannabis products covered and included in the Recall were tested for microbial contamination by Plaintiffs, marijuana safety compliance facilities, in accordance with Michigan law. The MRA couched its justification for the Recall in public health and safety. However, that was inaccurate; there was no public health or safety risk justifying the Recall at all.

2. The MRA cannot act on its own. Instead, it acts through its employees, specifically the named defendants. This case illustrates the extraordinary dangers created when a state administrative agency’s employees are allowed to regulate from the shadows without proper oversight by a neutral, detached decision maker and, worst of all, motivated by their own whims, political objectives, and biases.

3. Prior to the MRA’s Recall, Plaintiffs controlled the “lion’s share” of the cannabis testing industry, testing for between 60 to 70% of the state’s growers and producers. It provided high quality and accurate tests to its customers, which the market responded to by flocking to Plaintiffs for testing needs. While Plaintiffs do not know the named defendants’ exact motivations, the record evidence set forth below strongly suggests that the named defendants, acting in their

role as regulators, wrongfully targeted Plaintiffs for improper purposes such as, among other things, and upon information and belief, a desire to “level the playing field” so that all marijuana safety compliance facilities would get an equal share of the cannabis testing market. In other words, the Recall was the named defendants’ disguised means of reaching its desired political result that it could not achieve through the actual powers delegated to it under Michigan law.

4. By instituting the Recall, the named defendants achieved their desired goal. Among other things, the Recall cast Plaintiffs in a false, negative light with its customers, put significant financial strain on Plaintiffs due to the enormous financial liabilities associated with the Recall, and, ultimately, placed Plaintiffs in the precarious position of potentially having to shutter their doors. To make matters worse, the named defendants continued their improper vendetta against Plaintiffs’ business operations by summarily restricting and effectively suspending their licenses to test cannabis products for microbial contamination, meaning Plaintiffs *could not* even retest the samples that are subject to the Recall to mitigate the devastating economic effects the Recall had on its customers. In effect, the named defendants, through their jobs at the MRA, orchestrated a coordinated campaign to, among other things and as described below, upon information and belief, destroy Plaintiffs’ credibility and standing, drastically dilute its market share within the industry, and intentionally structured its campaign to prevent Plaintiffs from seeking any form of review or oversight that may hinder its overall objectives.

5. Plaintiffs seek to shed light on the activities that the named defendants had hoped to keep behind closed doors and to recover the significant economic damages Plaintiffs have suffered as a direct and proximate result of the named defendants abusing their power as regulators for their own political objectives.

PARTIES, JURISDICTION, VENUE

6. Plaintiff Viridis Laboratories, LLC (“Viridis Lansing”) is a Michigan limited liability company formed under the laws of the State of Michigan and conducts business through a laboratory established in the City of Lansing, Ingham County, Michigan.

7. Plaintiff Viridis North, LLC (“Viridis Bay City”) is a Michigan limited liability company formed under the laws of the State of Michigan and conducts business through a laboratory established in Bay City, Bay County, Michigan.

8. Although Plaintiffs share “Viridis” in their name, and have common principals, they are separate and distinct business entities with entirely different ownership structures.

9. Non-party MRA is a type I Michigan state agency established within the Michigan Department of Licensing and Regulatory Affairs (“LARA”) and is charged with implementing, enforcing, licensing, and overseeing compliance with Michigan laws relating to marijuana.

10. Desmond Mitchell is the Operations Director of the MRA. Mr. Mitchell is sued in his individual capacity.

11. Julie Kluytman is the Enforcement Division Director of the MRA. Ms. Kluytman is sued in her individual capacity.

12. Allyson Chirio is a Laboratory Scientist Specialist with the MRA. Ms. Chirio is sued in her individual capacity.

13. Claire Patterson is a Manager of the Scientific & Legal Section Enforcement Division of the MRA. Ms. Patterson is sued in her individual capacity.

14. The Court has jurisdiction because this matter concerns damages greater than \$25,000.

15. Venue is properly before the Court because the named defendants either reside in, work, or conduct business in Ingham County, Michigan.

16. Consistent with the rules of notice pleading in Michigan, the purpose of this Complaint is to put the named defendants on notice of claims consistent with the allegations contained herein and is not meant to be an exhaustive identification of each and every actionable act or omission committed by the named defendants. Plaintiffs may at times refer solely to the MRA, but any allegations related to the MRA should be read to include direct reference to all of the named defendants as the employees that carried out the improper and unlawful conduct alleged in this Complaint.

GENERAL ALLEGATIONS

BACKGROUND

17. Plaintiffs are marijuana safety compliance facilities licensed by the MRA under the Medical Marijuana Facilities Licensing Act (“MMFLA”) (MCL 333.27101, *et seq.*) and the Michigan Regulation and Taxation of Marijuana Act (“MRTMA”) (MCL 333.27951, *et seq.*) to sample and test adult-use and medical cannabis products.

18. The MRA regulates marijuana laboratories like Plaintiffs through the MMFLA and MRTMA.

19. Plaintiffs were founded by former Michigan State Police laboratory scientists with greater than 75 years combined experience working within a strictly regulated and nationally accredited forensic science industry, which included high volumes of marijuana testing.

20. Viridis Lansing received its license from the MRA to test medical marijuana on June 5, 2019, and its adult-use license on December 7, 2020.

21. Viridis Bay City received its license from the MRA to test medical marijuana on April 6, 2020, and its adult-use license on June 10, 2020.

22. The MRA requires marijuana safety compliance facilities to be accredited.

23. Plaintiffs use A2LA ISO 17025:2017 accredited methods. The A2LA is the leading accrediting body in the nation for cannabis testing laboratories.

24. Viridis Lansing received accreditation on July 23, 2020.

25. Viridis Bay City received accreditation on February 4, 2021.

26. Plaintiffs' research and development is led by Michele Glinn, Ph.D, F-ABFT, the former program coordinator for the Michigan State Police crime labs.

27. Dr. Glinn is a well-respected toxicologist around the country and testifies as an expert witness for prosecutors in 40 to 50 cases a year.

28. The A2LA performed a full review of the validation and Standard Operating Procedures ("SOPs") of Plaintiffs' testing methods prior to its accreditation.

29. Licensed marijuana safety compliance facilities like Plaintiffs are required to not only follow the requirements of the MMFLA and MRTMA, but also the rules promulgated by the MRA.

30. Under the MRA's Sampling and Testing Rules (the "Testing Rules"), a laboratory, which is defined to include marijuana safety compliance facilities like Plaintiffs, must perform various tests on batches of marijuana products. MAC R.420.301(m) and 305(3)(a).

31. The Testing Rules require that Plaintiffs "use analytical testing methodologies for the required safety tests in subrule (3) of this rule that are validated by an independent third party and may be monitored on an ongoing basis by the agency or a third party. In the absence of reference to compendia or published methods, Appendix K of Official Methods of Analysis authored by the Association of Official Analytical Chemists ["AOAC"]) must be published in full. The agency shall approve the validated methodology used by the laboratory and confirm that it produces scientifically accurate results for each safety test it conducts." MAC R.420.305(2).

32. It is necessary for the MRA to rely on accrediting bodies such as the A2LA and scientific organizations like the AOAC for accreditation and approvals because the MRA scientists lack requisite scientific knowledge to govern the testing labs themselves, a fact that the MRA has previously acknowledged. Attached as **Exhibit A** are emails between some of the named defendants and non-MRA associated scientists where the named defendants request explanation of data the named defendants lacked knowledge to analyze themselves.

33. The MRA, through Allyson Chirio, has historically and openly admitted that its scientists and employees have little-to-no experience or idea of what they are doing when it comes to regulatory oversight of marijuana facilities or testing methodologies. In fact, most recently, Ms. Chirio compared the MRA and its employees to infants and toddlers. Ms. Chirio stated that when the MRA took over the reins of regulating the cannabis industry in 2019 that it was like an infant (i.e., could barely function on its own and could not do anything for itself). Fast forward three years, Ms. Chirio compared the MRA to a toddler (i.e., can still barely function on its own but has learned some lessons from the past).

34. Plaintiffs implement and are known for employing state-of-the-art lab equipment and conducting accurate, correct, and reliable tests on cannabis products. Indeed, Plaintiffs consistently find ways to innovate their and other methodologies to create more accurate testing results. This has resulted in Plaintiffs developing a patent-pending method for cannabis potency analysis (the “Viridis Method”). The Viridis Method is not set forth here because of its protected status as proprietary and trade secret information.

35. As Plaintiffs’ regulatory body, the MRA, through some of the named defendants, has continuously monitored their testing methods, both in-person and via video, since Plaintiffs began operations. Over the course of years, the MRA has time and time again *observed* and *approved* Plaintiffs’ testing methodologies after conducting audits and monitoring its methods.

36. Plaintiffs have also consistently passed proficiency tests instituted by the MRA.

37. A proficiency test is a quarterly inter-laboratory comparison between competing marijuana safety compliance facilities. The purpose of the test is to verify that the labs are able to reach similar results when testing sample marijuana provided by the MRA.

38. Although the MRA requires marijuana safety compliance facilities to undergo proficiency testing, it does not publish the results of its testing. However, during a group question and answer session during one of the MRA's workshops in 2021, Executive Director Andrew Brisbo indicated that the MRA did "not see anything" out of the ordinary from a proficiency testing standpoint.

39. Viridis Lansing and Viridis Bay City have also successfully completed and passed external proficiency tests the previous two years as required annually by the MRA and the A2LA for accreditation purposes. These external proficiency tests are provided through Absolute Standards Inc. and NSI Lab Solutions, two approved, accredited third-party proficiency test providers recognized by the MRA.

40. Recently, in June 2021, Viridis Lansing successfully passed their annual accreditation surveillance assessment by the A2LA. This assessment included review of all of Plaintiffs' SOPs. (**Exhibit B**, A2LA Assessment).

PLAINTIFFS' COMPETITORS AND THE NAMED DEFENDANTS TAKE ISSUE WITH PLAINTIFFS' MARKET SHARE IN THE CANNABIS TESTING INDUSTRY

41. Because Plaintiffs provide accurate and reliable test results using the most up-to-date methods and equipment, the cannabis market, specifically growers and producers, have flocked to Plaintiffs to test their products. By 2021, Plaintiffs tested for between 60 to 70% of the cannabis market, meaning that 60 to 70% of all legal products on retail shelves have been tested by Plaintiffs.

42. The MRA, through the named defendants, took notice of Plaintiffs' large percentage of market share in the cannabis industry.

43. Upon information and belief, there are only nineteen medical and seventeen adult-use marijuana safety compliance facility licensees in Michigan. Viridis Lansing and Viridis Bay City hold two of the licenses, which means there are seventeen medical and fifteen adult-use non-Viridis related facilities that perform cannabis testing (the "competitors"). The competitors split the remaining 30 to 40% of the cannabis flower testing market.

44. Some of the competitors have taken issue with Plaintiffs' organic market share of the cannabis testing industry. Rather than out-competing Plaintiffs, some of the other facilities have indicated that they want to remove Plaintiffs from the market and industry entirely.

45. Several competitors have openly indicated to Plaintiffs and the MRA during open, public calls that they wanted to see Plaintiffs shut down and put out of business to open more market opportunities for themselves. Indeed, several competing marijuana safety compliance facility labs, including PSI Labs, Inc., Steadfast Labs, THC, and Infinite CAL Labs, have lobbed false complaints against Plaintiffs with the MRA instead of trying to out-compete Plaintiffs.

46. The MRA's (but really the named defendants') own internal political objective for the cannabis testing market is to ensure that all marijuana safety compliance facilities have a "fair share" of the testing market. In fact, during a recent webinar, Claire Patterson verified that the MRA's political objective is to ensure that there is not too much of a market concentration in one particular lab. Ms. Patterson put on a slide, which was part of the webinar, that the MRA is asking marijuana safety compliance facilities to "work together," that the MRA is seeking a "level playing field" between facilities, and takes issue with the fact that facilities are "not wanting to share proprietary methods." (**Exhibit C**, Slide). Simply put, the MRA and the named defendants *do not* want marijuana safety compliance facilities to compete in an open market where the most efficient,

up-to-date, and reliable lab wins. Instead, the MRA, through the named defendants, want a homogenized group of mediocre labs where innovation will be stifled because of their desire for labs to share proprietary information. While the MRA and the individual defendants may want the cannabis testing industry to engage in a race to the bottom, that is not how open markets work.

47. Upon information and belief, based on the named defendants' own stated policy goals and the vocal concerns of Plaintiffs' competing marijuana safety compliance facilities, the MRA took issue with Plaintiffs having a 60 to 70% market share of the cannabis testing industry.

48. The MRA has no authority to regulate or cap a marijuana safety compliance facility's share of the cannabis testing market. However, as explained below, upon information and belief, there are strong, well-documented patterns that show that the MRA, through the named defendants, has weaponized its own administrative rules and processes to reach its desired goal. The MRA and the named defendants have engaged in a concerted effort and campaign to artificially dilute Plaintiffs' market share in the industry or to remove Plaintiffs from the cannabis testing industry altogether. In either scenario, the result will be the same: the competitors will obtain a larger piece of the cannabis testing market.

THE MRA AND THE NAMED DEFENDANTS TARGET PLAINTIFFS FOR AN IMPROPER AND UNSUPPORTED RECALL

49. The MRA and the named defendants' most recent campaign against Plaintiffs began with a focus on the Viridis Method for potency analysis.

50. Around November 2020, the MRA inquired about the Viridis Method despite having seen it performed by Plaintiffs several times in the past.

51. On October 1, 2021, during a phone call between Julie Kluytman and Greg Michaud (Plaintiffs' CEO), Ms. Kluytman told Mr. Michaud that the MRA had received at least 15 complaints that the MRA was required to investigate.

52. Since November 2020, the MRA has attempted to prevent Plaintiffs from using the Viridis Method for potency analysis and has systematically attempted to retroactively disapprove its use. The MRA and Plaintiffs' dispute over this issue eventually resulted in the MRA filing several administrative complaints against Plaintiffs that are currently the subject of contested case hearings in the Michigan Office of Administrative Hearings and Rules.

53. On October 29, 2021, Assistant Attorney General, Risa Hunt-Scully, sent counsel for Plaintiffs an investigation report related to the administrative complaints that had been filed by the MRA. The report was dated September 27, 2021, by Allyson Chirio, and was approved by Claire Patterson on October 13, 2021.

54. The administrative complaints were dated August 25, 2021, and the "investigation report" was dated over a month later. The investigation report includes reference to an anonymous alleged licensed grower that claimed that Plaintiffs were inflating potency levels and guaranteeing growers that retests would pass. Plaintiffs engaged in no such conduct.

55. Upon information and belief, the MRA systematically sought to justify its potency complaints against Plaintiffs after the fact by lobbying other marijuana safety compliance facilities to file complaints. Nearly all of the "complaints" alluded to in the "investigation report" were received between the time the potency complaints were filed and when the "investigation report" was released.

56. The MRA has improperly used these unreliable complaints from "anonymous" competitors to justify their continued attacks against Plaintiffs.

57. In response, due to the MRA's continued unnecessary disruption to Plaintiffs' business, on October 25, 2021, Plaintiffs used the formal and appropriate administrative process found in the MMFLA to file a complaint against the MRA ("Unnecessary Business Disruption

Complaint”). MCL 333.27302(i); MAC R. 420.706(1). A copy of the current, controlling complaint, absent exhibits, is attached as **Exhibit D**.

58. The MRA sat on responding to Plaintiffs’ Unnecessary Business Disruption Complaint for three weeks. Plaintiffs were ultimately required to inform the Assistant Attorney General that if the Unnecessary Business Disruption Complaint was not properly processed that a Complaint for Mandamus would be filed. The Complaint was submitted to the Michigan Office of Administrative Hearings and Rules the following day.

59. Consistent with the MRA’s attempts to prevent Plaintiffs from using the Viridis Method for potency analysis, on October 12, 2021, during the pendency of the administrative complaints that the MRA had filed against Plaintiffs, Claire Patterson sent an e-mail to Plaintiffs with investigation requests for outstanding and “current, on-going investigations.”

60. The investigation requests from Ms. Patterson included 18 requests, consisting in part, of the following:

Currently Outstanding Investigation Requests

- A. Video footage of Viridis Bay City;
- B. Potency prep sheets for 6 specific samples;
- C. Follow up request for calculation sheet for mold, pests and powdery mildew along with specific questions related to those calculations;
- D. Request for Method analysis added to Certificate of Analysis;

Currently Outstanding Method /Validation Requests

- E. The request states that in order to approve any updates made to the potency method (SOP LOM-7.1a Cannabinoid Analysis by HPLC-DAD), that is any updates that alter the method from the reference method, we require a complete validation to AOAC Appendix K. This also includes updates to the prep method that was approved by the MRA in January 2020.
 - i. Submit a validation report, with an appropriate experimentation, statistical power, statistical design (e.g. RCBD or CRBD) and statistical analyses (e.g. ANOVA, Turkey HSD or Fisher LSD) to enable acceptance of the null hypothesis (H₀).
 - ii. Alternatively, the laboratory may opt to run the reference method. If the laboratory opts to return to the reference method, they must also adhere to the appropriate SMPR’s for the Potency.
- F. Microbial Testing approval request for SOP matrix expansion;
- G. Requirement for additional information about Terpenoid Analysis;

- H. Request for information related to a requested Chemical Residue SOP matrix expansion;

New Investigation Requests

- I. Request for Initial Demonstration of Capability (IDOC) for all technicians performing foreign matter analysis;
 - i. The documents(s) used to train staff about identifying foreign matter as well as how to calculate foreign matter for the entire sample;
- J. Request for photos of samples which contain foreign matter detected in flower samples for the last 6 months;
- K. Request for all calculations performed for foreign matter for that past 30 days that determine whether a sample is pass or fail;
- L. Request for information about two specific METRC samples asking for amount left in storage;
- M. Request for the SOP currently used by staff to complete foreign matter analysis;
- N. Request for an instrument read-out of all tests performed on both the gene-up and aria platforms within the past 3 months;
- O. Request for Incubation logs for all Aspergillus tests performed in the month of September;
- P. A complete list of all currently employed methods, the date of the last update, and the date that the method was approved by the MRA, as well a copy of all current SOPs currently in use;
- Q. A copy of all internal audits performed in 2020-2021;
- R. A daily schedule of when analyses are typically performed, or if ongoing throughout the day, please let us know;
 - 1. In addition, a request for several dates and time during the next two weeks for both Viridis locations when all technicians/analysts can be available for interview.

A copy of the above requests is attached as **Exhibit E**.

61. METRC is Michigan's statewide seed-to-sale marijuana tracking system that serialized tags attached to every plant – and labels attached to wholesale packages to track marijuana inventory. <https://www.michigan.gov/mra/0,9306,7-386-100002-510865--,00.html>

62. METRC is a third party that is contracted by the state.

63. On October 19, 2021, Plaintiffs received a returned ticket from METRC stating, “per the MRA, ‘Please ask for the equipment maintenance log of all incubators along with least temperature verification performed by an outside company.’” The MRA has *never* requested this information in the past and arbitrarily requested Plaintiffs perform additional tests by outside vendors without explanation as to why the test was being performed.

64. The MRA and the named defendants have effectively weaponized METRC by requiring METRC to now act as an enforcement arm seeking information on behalf of the MRA that is outside of its intended purpose.

65. Subsequent to receiving the above requests from the MRA, on October 21, 2021, the MRA indicated in an email to Plaintiffs that it intended to conduct full-day audits at both Viridis Lansing and Viridis Bay City. The MRA intended to “perform audits of the methods and procedures in real time” and to ask “questions related to the method and SOP.” A copy of the MRA’s email exchange and proposed schedules is attached as **Exhibit F**.

66. Viridis Lansing followed up on the MRA’s email request and inquired if the audits were for “quality assurance” or “post-complaint” investigation. The MRA responded that it would be “quality assurance audits, post-complaint audits, and investigatory audits.” (**Exhibit F**).

67. On October 25, 2021, the MRA escalated its campaign against Plaintiffs by revealing to Plaintiffs’ competitors that Viridis was under investigation via e-mail. In that e-mail, the MRA directed that 10 of Viridis Lansing’s previously tested samples were to be retested as part of the audit by other marijuana safety compliance facilities for microbial testing, including aspergillus, total yeast and mold, foreign matter, and pesticides. The MRA “randomly” selected several of the competitors for the audit testing. Copies of the sample audit notices from METRC are attached as **Exhibit G**. The MRA did not require any sample from Viridis Bay City to be retested as part of this audit request.

68. The MRA does not have its own safety compliance facility, so it selected “random” testing facilities to re-test Plaintiffs’ previously tested cannabis products.

69. Several of the marijuana safety compliance facilities that the MRA, through the named defendants, “randomly” selected to perform audits of Viridis Lansing’s samples are the same competitors that have consistently complained about Plaintiffs, as a whole, having a large

portion of the market for cannabis testing and have publicly stated that they want to see Plaintiffs put out of business.

70. Unsurprisingly, 6 out of 10 of Viridis Lansing's previously tested samples that were sent to its competing labs as part of the October Audit were ultimately "failed."

71. On October 26 and 27, 2021, the MRA, through its employees Noah Rosenzweig, Patrice Fields, and Defendants Allyson Chirio and Claire Patterson, conducted its on-site "audits" at Viridis Lansing and Viridis Bay City's respective facilities (the "October Audits"). At the time of the October Audits, the MRA knew and had received a copy of the complaint attached as **Exhibit D**.

72. During the October Audits, the MRA observed Plaintiffs perform numerous tests on cannabis samples, including microbial analysis for aspergillus, total yeast and mold, foreign matter, and pesticides.

73. On November 15, 2021, almost three weeks *after* the MRA completed the October Audits, it released and forwarded to Plaintiffs its Onsite Audit Findings (collectively the "October Audit Findings"). (**Exhibit H**, Viridis Lansing's Onsite Audit Findings; **Exhibit I**, Viridis Bay City's Onsite Audit Findings).

74. Unlike the MRA's prior practice, the October Audit Findings did not provide Plaintiffs any opportunity to respond to the alleged deficiencies in its practices or testing procedures. Instead, on the same day, the MRA and the named defendants, during a Teams phone call, notified Plaintiffs that it was going to recall all of Plaintiffs' previously tested cannabis products that were tested between August 10, 2021 and November 16, 2021.

75. Ever since the MRA first mentioned the possibility of the Recall on November 15, 2021, the MRA and the named defendants have articulated (via phone and/or Teams or Zoom, but still not in writing as required under the rules) only two bases for the Recall. First, they asserted

that Plaintiffs had failed to keep a log book showing that they had kept the samples tested for aspergillus and other microbials in its bioMerieux incubator (a machine required for the test) at a certain temperature for 24 to 48 hours. After Plaintiffs explained, and the MRA and the named defendants acknowledged, that such logs are not required by statute, rule, any informal MRA guidance, or Plaintiffs' SOPs, at that point the MRA and the named defendants shifted and said the Recall was warranted because it asserted that Viridis Lansing's 6 out of 10 retested and "failed" samples evidenced issues with the accuracy of Viridis Lansing's prior microbial analysis tests, specifically for aspergillus.

76. Neither of the two grounds the MRA or the named defendants provided to Plaintiffs for the Recall are supported by any applicable law or rule. In fact, Plaintiffs never deviated from the method accredited by A2LA and the SOP approved by the MRA and which it observed Plaintiffs perform numerous times over the course of two years. Indeed, not once did the MRA or the named defendants comment on the lack of an incubator log until October 25, 2021. Then they waited over three weeks—during which time a significant amount of Viridis-tested product was sold and consumed—before abruptly announcing the Recall and claiming that the lack of incubator logs was a health and safety concern.

77. The MRA and the named defendants proposed to issue the Recall for between August 10, 2021 and November 16, 2021, which is completely arbitrary. This was pointed out first in a phone call with the MRA, on November 16, 2021. Plaintiffs explained that it had never kept log books since its inception, and, if that was the basis for a recall, then the proposed recall would necessarily include all microbial tests ever completed by every marijuana safety compliance facility within the industry. During that conversation, Desmond Mitchell told Plaintiffs that he was "doing them a solid" by not making the Recall much broader in scope.

78. The fact that the MRA knew and approved Plaintiffs' procedure for microbial testing, including aspergillus, which has never included keeping logs for the incubator shows that this Recall has nothing to do with public health and safety.

79. While Plaintiffs had originally thought that the MRA and the named defendants had decided on a recall within three weeks leading up to the November 15, 2021 call, they now know that the MRA the named defendants actually intended to recall Plaintiffs' tested cannabis products as far back as September, 2021. The October Audits were merely a pretext to obtain information to justify the Recall. Attached as **Exhibit J** are emails between the named defendants and others where they are inquiring on factual bases to issue the Recall months *before* it was issued.

80. Rather, upon information and belief, the timing of the Recall was intended to impose maximum damage, as it came just before the busy Thanksgiving holiday and so-called "Green Wednesday," which is among the busiest sales days of the year for cannabis retail locations.¹

81. As stated above, the MRA continuously monitors Plaintiffs and has been fully aware of its SOP, which at that time did not include keeping log books.

82. The MRA has approved this method and the A2LA has done an accreditation of the method, which was approved on December 1, 2021.

83. In response to an e-mail questioning the scope of the proposed Recall on November 17, 2021, Mr. Mitchell stated "[t]he investigation is still ongoing. As part of that investigation, we'll determine if the recall should be expanded as you've indicated [*this was in response to Viridis counsel pointing out that Viridis has never kept log books and the MRA has known that since it*

¹ <https://www.forbes.com/sites/lindseybartlett/2020/11/30/cannabis-sales-in-the-us-soar-on-green-wednesday/?sh=10f8aa27625d>

first started testing]. If it does, we expand the recall. However, as Kevin [Blair] has pointed out before this is a public health and safety issue and we need to act on this as soon as possible.” (**Exhibit K**, Email Correspondence between MRA and Viridis’ Counsel).

84. Upon information and belief, many—if not all—marijuana safety compliance facilities have not or do not keep log books for their incubators for microbial analysis, which the MRA knew about but has never issued any recall related to this failure.

85. The MRA’s position is not supported by the evidence before it, and was specifically designed to set Plaintiffs up to fail.

86. Over the course of several days, the MRA, through its various representatives, and Plaintiffs, through their counsel, corresponded about the proposed Recall and the grounds for said Recall. Copies of those correspondences are attached as **Exhibit K**. The most egregious parts of the MRA’s communications with Plaintiffs are highlighted in the body of this Complaint, but the Court should read **Exhibit K**, in its entirety, to understand the full context of the situation.

87. In addition to the written communications attached as **Exhibit K**, the MRA and the named defendants also had numerous telephone conversations with Plaintiffs’ counsel. The MRA, through Mr. Mitchell, indicated that a lack of log book, on its own, would not warrant a recall. He indicated that the MRA was making the Recall because of the alleged deficiencies in Viridis Lansing’s 10 samples that were rested by the competitors.

88. Plaintiffs challenged the MRA’s reliance and means of retesting Viridis Lansing’s 10 samples as part of the October Audits. By using the competitors, especially those who have publicly indicated they desire to see Plaintiffs shutter their doors, the MRA placed Plaintiffs on the path to failure. (**Exhibit K**).

89. Plaintiffs also challenged the MRA’s reliance on the absence of log books. A marijuana safety compliance facility is *not* required by statute, administrative rule, or even the

MRA's own technical guidance to keep a log book of hours in an incubator or temperature. Nor does the AOAC (the organization referenced and relied upon by the MRA for scientific guidance) or the incubator's manufacturer, bioMerieux.

90. The MRA observed Plaintiffs perform microbial analysis testing, including for aspergillus, for over two years and has *never* raised concerns of Plaintiffs not having a log book for its incubation process. It curiously now takes issue with this fact. In July 2021, the MRA conducted a proficiency test of Viridis Lansing and approved all 60 aspergillus samples tested by Viridis Lansing using the exact procedure that the MRA now claims is unreliable. (**Exhibit L**, Method Approval).

91. Viridis Bay City also challenged the breadth of the MRA's proposed Recall because the MRA did *not* request that it send *any* samples for audit. Put simply, the only grounds the MRA had for recalling Viridis Bay City's tested products was the lack of log books, which the MRA consistently indicated was not sufficient, on its own, to warrant a recall. Yet, the MRA issued the recall for Viridis Bay City anyway, merely because it has the word "Viridis" in its name.

92. Plaintiffs also challenged the MRA's proposed Recall on the grounds that it was overbroad because it included samples (around 10% of the cannabis products covered by the Recall) that were *not* tested for microbials and would have nothing to do with the alleged deficiencies identified in the October Audits.

93. When the MRA would not change its position on the Recall based on Plaintiffs' own correspondence, Viridis contacted representatives from the AOAC and bioMerieux, the vendor of the aspergillus testing platform known as GeneUp, to learn their positions on the matter, especially as to the MRA's use of several of the competitors to perform the sample audits.

94. Patrick Bird, a widely respected consultant from the AOAC² that the MRA routinely relies on for expertise, concluded that the MRA's methodology was scientifically flawed and would not be sufficient to support a Recall. In his e-mail to the MRA, on November 17, 2021 trying to educate the MRA on why a Recall would be inappropriate stating the following:

The additional testing of materials at other labs is not something that I believe supports a recall as there are many factors in play that may have lead to the different results (same batch but different test portions analyzed, time gaps in analysis from one lab to another, etc).

(Exhibit K).

95. Maria McIntyre, from bioMerieux,³ mirrored the consultant from the AOAC's position as well. She indicated that the methodology used by the MRA was not able to produce scientifically accurate or reliable results and that, in essence, the only thing that the MRA was basing its recall on was the absence of log books. In an email to MRA, on November 17, 2021, she also tried to educate the MRA on why a recall based on its reasoning was flawed:

1. Methods utilized have AOAC approval. This data collection usually includes robustness data that may or may not be a change in temperature. Please know, we are working to confirm if this data is available from the work for AOAC. This may take time to capture as I am collaborating with John Mills- Scientific Affairs Manager and Dr. Ron Johnson- former AOAC President.

2. ISO 17025 accreditation impacts the discussion as ISO sets the benchmark for the quality standards within accredited laboratories. If a recall is generated under these circumstances it's a reflection of a gap in ISO accreditation and does not relate to AOAC or the method itself. The lab has completed training on the method reflected in the training certificates and demonstrated via the ISO 17025 accreditation process.

² The MRA relies on the AOAC as part of its Testing Rules, which require licensees to follow Appendix K of the AOAC. MAC R. 420.305(3).

³ bioMerieux's incubator is the same platform used by all of the labs that the MRA sent the samples to that tested Viridis' samples. bioMerieux has more expertise on their platform and the reliability of these tests than anyone else.

3. When there is uncertainty in results either retesting or confirmation testing generally holds greater value than a multi-lab study. In such a study, there are many variable in the equation leading to variability.

4. The iso files have been reviewed and the assay appears to be running properly. The files have been transferred to the R&D team who created this assay for a 2nd opinion and to determine if other areas require addressing.

(Exhibit K).

96. Plaintiffs tried to reason with and educate the MRA up until the very last minute. Not only did the two most reliable subject matter experts opine that the Recall was inappropriate based on the flawed retests of Viridis Lansing's tested cannabis products, Plaintiffs offered for the MRA and the named defendants to review the video evidence that it already had in its possession and to supplement that with further video so that the MRA could confirm that Plaintiffs had properly tested for microbial contamination, including aspergillus, and all samples were incubated for the required time. The MRA and the named defendants refused to look at the video evidence.

97. Notwithstanding irrefutable evidence that the MRA's rationale for a recall was not based in science, the MRA refused to budge and issued the recall bulletin on November 17, 2021. **(Exhibit M, Recall Bulletin)**. Interestingly, the MRA used a bulletin to recall the Viridis' previously sampled products even though said action does *not* have the force of law. MCL 24.232(5).

THE RECALL CREATED CHAOS AND DAMAGED PLAINTIFFS' REPUTATION AND STANDING IN THE CANNABIS INDUSTRY

98. Because Plaintiffs tested for 60 to 70% of the cannabis industry that means the Recall covered 60 to 70% of all cannabis products in the market. The Recall created chaos and panic within the cannabis industry. Growers, producers, and retailers scrambled trying to get their products back on the market. Smaller growers and retailers voiced their concerns over the lack of product and indicated to the MRA, Plaintiffs, and others in the cannabis industry that they will not be able to survive because of the product and cash flow interruptions caused by the recall.

99. As previously stated, the Recall is overbroad. It covers not only all of Plaintiffs' previously tested products, including products that were tested for items unrelated to microbials analysis and were thus unrelated to the MRA's concerns, but also products from Viridis Bay City, which, again, did not provide *any* samples for audit because they were not requested by the MRA.

100. The Recall included over 64,000 lbs. of flower totaling over \$229 million using the average retail price per lbs. between August 10, 2021 and November 16, 2021.

101. Over 10% of the recalled cannabis products were not tested for microbial analysis.

102. The MRA's recall is improper in both scope and substance.

103. Upon information and belief and reasonable inference, the MRA, and more specifically the named defendants, issued the Recall, at least in part, as retaliation for Plaintiffs filing the complaint attached as **Exhibit E**. The Recall was intended to smear Plaintiffs' standing and reputation within the cannabis industry and simultaneously achieve Plaintiffs' political objective of limiting Plaintiffs' market share.

104. Many of Plaintiffs' customers learned about details of the Recall prior to it being issued on November 17, 2021, which upon information and belief, was leaked from within the MRA by one or more of the named defendants.

105. Upon information and belief, the competitors were celebrating the recall prior to November 17, 2021.

**THE MRA SUMMARILY RESTRICTED PLAINTIFFS' LICENSES SO THEY COULD
NOT COMPLETE MICROBIAL ANALYSIS ON THE RECALLED CANNABIS
PRODUCTS**

106. To add insult to injury, after the MRA issued the Recall notice, it indicated to Plaintiffs in an email on DATE that because it had "corrected" the log book issue by implementing said process into its microbial testing process, that it was approved to begin re-commence microbial analysis testing. An email evidencing this fact is attached as **Exhibit N**.

107. The MRA then *changed its position* in less than 24 hours and indicated that Plaintiffs could only test for aspergillus. (**Exhibit N**). The MRA then changed its position *again* by informing Plaintiffs' customers, without informing Plaintiffs, that Plaintiffs could not perform *any microbial testing* as a result of the Recall.

108. The MRA's Recall notice put growers, producers, retailers, and others connected to Plaintiffs in chaos because of its breadth and unexpectedness. The Recall, by its terms, allows those affected by it to have the product retested for microbial analysis.

109. Several of Plaintiffs' existing customers called the MRA to verify that Plaintiffs can perform the retest. In response, the MRA responded that Plaintiffs were prohibited from performing *any* analysis related to microbials. Plaintiffs' customers informed Plaintiffs of the MRA's position and statements on its ability to perform microbial analysis.

110. The MRA told Plaintiffs' customers one thing and Plaintiffs another. They both cannot be right, and the defendants deliberately took contrary positions to cause even more chaos and damage to Plaintiffs.

111. The MRA's actions related to microbial testing are contrary to the promulgated rules, which do not allow the MRA to unilaterally suspend or restrict a previous approval of a testing methodology or a marijuana safety compliance facility's license.

112. The MRA refused to provide Plaintiffs with adequate, written, or clear guidance on what it may do moving forward and actively sought to hinder their ability to address the recall with their customers.

113. The Recall, by its very terms, allows cannabis products to be retested for microbial analysis. (**Exhibit M**). Because the MRA restricted and prevented Plaintiffs from conducting microbial analysis, Plaintiffs sought guidance from the MRA on what is needed to get re-authorization to test for microbials such that it can assist its customers.

114. In subsequent conversations with the MRA, it sent Plaintiffs a “check list” of items that needed to be completed prior to it re-authorizing Plaintiffs to complete microbial analysis. During a zoom call, the MRA revealed that the check list was even longer than originally anticipated, but represented that only the items listed in bold needed to be completed for Plaintiffs to get up and running. In a follow up email, Plaintiffs sought to verify what needed to be completed on the checklist (not the entire list but only bolded items). However, Julie Kluytman changed the MRA’s position yet again, moved the goal posts back, and indicated that *everything* on the checklist needed to be approved before Plaintiffs could re-commence microbial testing. (**Exhibit K**).

115. Plaintiffs managed to complete or substantially comply with every item listed on the checklist and sought the MRA’s approval the following day. The MRA nevertheless rejected Plaintiffs’ efforts and demanded that it start its efforts over from scratch.

116. As of November 22, 2021, and subsequent to the unlawful Recall, the MRA is now allowing growers to have samples that Plaintiffs had originally tested submit new samples to other safety compliance facilities to be retested, and treating the Plaintiffs’ test results as failed tests.

117. The MRA is requiring these retests to have two consecutive passes and then allowing the growers to take the products to market.

118. These retests include samples that Plaintiffs have tested that have been homogenized, cross-contaminated with unground foreign matter, had spatulas and had tweezers poked in the sample during the initial testing, and overall have been adulterated during the testing process.

119. The MRA is diverting from each marijuana safety compliance testing facility’s approved SOPs and the MRA’s own rules. *See, e.g.*, MAC R.420.306 (“A failed marijuana product must pass 2 separate tests *with new samples* consecutively to be eligible to proceed to sale or

transfer.”) (emphasis added); *Sampling and Testing Technical Guidance for Marijuana Products*, MRA, July 1, 2021, p 25, https://www.michigan.gov/documents/mra/Sampling_and_Testing_Technical_Guidance_for_Marijuana_Products_694124_7.pdf, (“A failed marijuana product must pass 2 separate tests with *new samples* consecutively to be eligible to proceed to sale or resale.”).

120. These retests, which are using non-pristine samples, have no scientific value or reliability. Upon information and belief, the MRA will use these faulty results to again punish Plaintiffs by questioning their testing of the original, not new, samples. This is especially true because, as described below, Plaintiffs have discovered that the MRA has knowingly allowed illicit market cannabis to be sold in provisioning centers that may have adulterated Plaintiffs’ (and other marijuana safety facilities’) tested cannabis products.

121. The MRA’s conduct cannot be viewed in a vacuum. It had stated publicly that it did not want a concentrated cannabis testing industry, and over the course of about one year, has specifically targeted Plaintiffs for various “violations” that it cannot support with any substantial or reliable evidence.

122. Upon information and belief, the MRA’s conduct was carried out by and amongst the named defendants to target Plaintiffs because of their market share in the cannabis testing industry.

123. Upon information and belief, the MRA’s conduct was carried out in retaliation for Plaintiffs using the proper and appropriate administrative channels for addressing its grievances with the MRA.

124. The MRA has significantly deviated from prior practice when dealing with violations of this nature, as explained below, opting to institute the largest cannabis product recall

in the state's (and the regulated cannabis industry's) history. By doing so, it has discredited Plaintiffs, their methods, and their principals.

125. A substantial number of Plaintiffs' customers jumped ship to other marijuana safety compliance facilities to get their products on the market.

126. The MRA and the named defendants' wrongful conduct is the direct cause of all of this.

127. The MRA and the named defendants' above conduct effectively suspended or restricted Plaintiffs' licenses under Michigan law because they prohibited Plaintiffs from continuing to operate their business.

128. The MRA consistently took the position that its Recall is warranted because, among other things, the public health and safety was at risk and, by extension, allowing Plaintiffs to do *any* microbial testing puts the public's health and safety at risk. In these circumstances, the MRA should have followed the procedures and processes set forth by statute and administrative rule to summarily suspend Plaintiffs' licenses. MCL 24.292; MAC R. 420.705(1)

129. The MRA did not follow the correct procedures to suspend Plaintiffs' licenses; indeed, the MRA specifically refused to follow the correct procedures and instead insisted on constructively suspending and actually restricting Plaintiffs' licenses without any due process.

130. Upon information and belief, the MRA and the named defendants orchestrated its above described efforts in a manner to prevent Plaintiffs from obtaining any form of relief from an administrative proceeding *or* judicial review. If the correct procedures would have been followed by the MRA, then Plaintiffs would have been afforded notice of their license suspensions and an opportunity to contest said suspensions.

131. The MRA and named defendants' conduct is excess, unnecessary regulatory overreach and abuse that has significantly disrupted Plaintiffs' business operations and their operations as a marijuana safety compliance facility.

132. The above allegations, taken together and under the totality of the circumstances, evidence the MRA, through the named defendants, have continued to take step after step to interfere with Plaintiffs' business and effectively suspend and actually restrict their licenses without following the proper procedures required by law, thereby depriving Plaintiffs of a clear right to relief from a neutral, detached, and fair fact finder.

133. The MRA and the named defendants' actions interfered with and impaired Plaintiffs' legal rights and privileges.

134. The MRA and the named defendants' conduct is and was contrary to its own regulations and Michigan law.

**PLAINTIFFS FILE SUIT AGAINST THE MRA IN THE COURT OF CLAIMS AND
THE COURT OF CLAIMS PRELIMINARILY ENJOINED ENFORCEMENT OF THE
RECALL AGAINST VIRIDIS BAY CITY**

135. Plaintiffs filed a Verified Complaint in the Court of Claims against the MRA on November 22, 2021, seeking, among other things, an injunction enjoining the MRA from enforcing the Recall.⁴

136. Plaintiffs also filed a motion for temporary restraining order and preliminary injunction to enjoin the Recall while their case against the MRA was pending.

137. On December 1 and 2, 2021, the Court of Claims held evidentiary hearings on Plaintiffs' motion for temporary restraining order and preliminary injunction.

⁴ Plaintiffs also filed suit against the named defendants. However, they were dismissed from the case, without prejudice, due to lack of subject matter jurisdiction.

138. During the evidentiary hearing, Claire Patterson testified that the MRA had received 18 “adverse reactions” that she asserted were “associated” with Plaintiffs’ tested cannabis products (but did not produce actual evidence of the alleged “adverse reactions” at the hearing). She also testified that some of Plaintiffs’ cannabis products were failing retests at other labs, thereby evidencing the “proprietary” of the recall. As explained below, both of these statements turned out to either be entirely false or seriously lacking in credibility or reliability.

139. On December 3, 2021, the Court of Claims granted in part Plaintiffs’ motion for temporary restraining order and preliminary injunction. It enjoined the Recall as to Viridis Bay City, but allowed it to move forward as to Viridis Lansing.

140. The Court of Claims has now permanently enjoined the MRA from enforcing the Recall against Viridis Bay City because it found that the MRA had violated Plaintiffs’ substantive due process rights under the Michigan and United States Constitutions as the Recall related to Viridis Bay City was wholly arbitrary.

141. The Court of Claims’ permanent injunction is telling because it shows that the MRA, and by extension the named defendants, violated (at minimum) Viridis Bay City’s clearly established constitutional rights.

142. Plaintiffs had a clearly established right to be free from wholly arbitrary government action. The named defendants knew of that right, but chose to disregard it and issue the Recall anyways.

143. Plaintiffs also had clearly established rights to notice and an opportunity to be heard before a neutral, detached decision maker, and a written notice of findings prior to being deprived of their property or liberty interests. The named defendants knew of those rights as well, but again chose to disregard them and issue the Recall and summarily restrict Plaintiffs’ licenses without

notice, an opportunity to be heard before a neutral decision maker, or an explanation of their findings.

144. Plaintiffs also had a clearly established right to not be treated differently than other similarly situated marijuana safety compliance facilities. However, the named individuals also violated that right by treating Plaintiffs differently than other marijuana safety compliance facilities and make its decisions based on their animus and ill-will instead of reason.

145. As explained below, the named defendants are liable to Plaintiffs for their flagrant violations of Plaintiffs' clearly established constitutional rights.

THE MRA DISCOVERS POST-RECALL THAT ITS GROUNDS FOR INSTITUTING THE RECALL WERE BASELESS, PLAINTIFFS UNCOVER THAT THE "ADVERSE REACTIONS" REFERENCED BY THE MRA WERE ENTIRELY FALSE AND THAT THE MRA ACTIVELY AVOIDS ENFORCING MARIJUANA SAFETY LAWS FOR ILLICIT PRODUCT

146. Immediately following the Recall, and while Plaintiffs' motion for temporary restraining order and preliminary injunction was pending in the Court of Claims, the MRA, through Ms. Patterson, sought assistance from Ms. McIntyre of bioMerieux to interpret Plaintiffs' Gene-Up aspergillus testing data. (**Exhibit A**). The purpose of Ms. Patterson seeking Ms. McIntyre's assistance was to *post hoc* justify the Recall. Ms. Patterson needed Ms. McIntyre to interpret the data because Ms. Patterson, herself, could not interpret or understand the data.

147. Ms. McIntyre interpreted Plaintiffs' data and, unsurprisingly to Plaintiffs, found that (1) Plaintiffs' instruments were working properly; (2) Plaintiffs' aspergillus data was correctly generated; and (3) Plaintiffs had interpreted the data properly. In other words, the Recall was baseless. They had no data to support the Recall other than its improper use of the 6 failing retested samples as part of the October Audits (which, again, violate the MRA's own technical guidance).

148. Likely in light of the MRA's failure to justify the Recall *post hoc*, the MRA and the named defendants undertook concerted efforts to continue their orchestrated campaign against Plaintiffs.

149. The MRA and the named defendants strategically leaked investigative material (contrary to Michigan law) to put public pressure on Plaintiffs' business operations. Indeed, MLive ran what can only be described as a "hit piece" on Plaintiffs following the Court of Claims enjoining part of the Recall. (**Exhibit O**, Article). It describes cannabis products tested by Viridis as, among other things, "moldy" or "contaminated." MLive indicates that it received the information forming the basis of its article from the MRA following a FOIA request submitted to the MRA on December 14, 2021. The MRA almost always takes at least a week to respond to FOIA requests. But for this piece, the MRA somehow managed to have all documents prepared and release to MLive in *a single day*. The only conclusion that can be drawn from this is that the MRA made a targeted release to negatively affect Viridis' business operations.

150. The MRA also made sure to strategically highlight and release information to MLive and other "friendly" presses that there have been 18 "adverse reactions" to products associated with Plaintiffs' tested cannabis products. Like the "hit piece" referenced above, all of these stories cast Plaintiffs in a negative and false light.

151. Plaintiffs sought discovery concerning the Recall and the MRA's strategic leaks of information to the press and claims that there were 18 adverse reactions associated with Plaintiffs' tested cannabis products.

152. During depositions, other MRA employees (not the named defendants) verified that the MRA did *not* request or look for adverse reaction complaints by consumers prior to the Recall and, instead, only sought them after the Recall was issued and in preparation for the hearing on

Plaintiffs' motion for temporary restraining order and preliminary injunction in the Court of Claims.

153. Plaintiffs also learned that there was nothing substantiating or connecting the alleged 18 "adverse reactions" to Plaintiffs' tested cannabis products. In fact, there was no credible link to Plaintiffs' tested cannabis products at all, and nothing came from the MRA's investigation into the 18 "adverse reaction" complaints identified by the MRA. However, the MRA tellingly did not release the results of its "investigation" into the alleged 18 "adverse reaction" complaints and chose to instead leave that cloud hovering on Plaintiffs' reputation.

154. Plaintiffs also uncovered a revelation about the MRA's concern for public health and safety, or more accurately lack thereof. Several other MRA employees testified at their deposition (under oath) that investigators have found literal trash bags of illicit, untested cannabis products at provisioning centers. Illicit product means product that is not grown by a licensed grower, not tested by a marijuana safety compliance facility, and not packaged or processed by a licensed processor. There is no tagging, and no means to track the origins of the product. In other words, it's the equivalent of cannabis traditionally purchased on a street corner. There is no way to tell if it contains microbial contaminations like aspergillus (the exact microbial the MRA used as a pretext to issue the Recall) or any other safety concerns including carcinogenic pesticides and heavy metals because it was *not* tested.

155. This is concerning to Plaintiffs because the MRA relied on alleged "failed retests" for products that were at provisioning centers to justify *post hoc* that the Recall was justified on health and safety grounds. However, with Plaintiffs' tested cannabis products being exposed to non-pristine samples that have not undergone *any* testing, or the illicit product being mixed in with tested products, any reliance on "retests" would be scientifically flawed because there is no control in place to ensure there is no cross contamination.

156. The most shocking revelation from discovery was one other MRA employee testified that the MRA Executive Director, Andrew Brisbo, knows about the trash bags full of illicit cannabis products in provisioning centers, and he has instructed the enforcement division of the MRA to *not* seize the illicit cannabis products, even though the mere presence of this untested product on licensed premises is a clear licensing violation and obvious health and safety concern. Simply put, the MRA's own Executive Director has knowingly allowed illicit, untested cannabis products, with no guarantee that they are safe for consumption, to be consumed by consumers. These activities undermine the entire point of regulating cannabis products at all.

157. More frustrating to Plaintiffs is that the MRA justified the Recall based on public health and safety. But obviously the MRA's concern for public safety is based on the situation, the licensee it may or may not effect, and, worst of all, the political convenience of the situation.

158. Plaintiffs have suffered significant economic harm as a result of the MRA being weaponized by the named defendants to achieve their own political objectives and carry out their personal vendetta.

159. Plaintiffs are entitled to the relief sought in this Complaint.

COUNT I
42 USC 1983
VIOLATION OF PLAINTIFFS' PROCEDURAL DUE PROCESS RIGHTS UNDER THE
FOURTEENTH AMENDMENT OF THE UNITED STATES CONSTITUTION
(ALL DEFENDANTS)

160. Plaintiffs reassert and reallege the preceding paragraphs as if fully set forth herein.

161. The Fourteenth Amendment to the United States Constitution provides in Section 1 that no state shall "deprive any person of life, liberty, or property, without due process of law." US Const, Amend XIV, § 1.

162. The fundamental tenets of the procedural protections afforded by the United States Constitutions are notice and an opportunity to be heard before an impartial decision maker at a

meaningful time and a meaningful manner. *Reed v Reed*, 265 Mich App 131, 159; 693 NW2d 825 (2005).

163. Plaintiffs have a vested property interest in their licenses as a marijuana safety compliance facility to test cannabis products and a liberty interest to engage in their chosen profession and line of work.

164. The MRA violated Plaintiffs' procedural due process rights.

165. As explained above and alleged throughout this Complaint, Plaintiffs were denied every procedural protection afforded by the due process clause of the United States Constitutions.

166. Plaintiffs were not provided with notice of the MRA's intent to restrict and effectively suspend their licenses relating to microbial analysis, which occurred from November 17, 2021 through at least November 24, 2021. Nor were Plaintiffs' provided an opportunity to be heard before the restriction and effective suspension of their licenses.

167. Plaintiffs were not afforded an opportunity to be heard to challenge the appropriateness of the MRA's Recall of their tested marijuana products. This is especially true for Viridis Bay City. As explained above, Viridis Bay City's tested cannabis products were *not* tested by other facilities, meaning the MRA's inclusion of its tested cannabis products in the recall was wholly arbitrary.

168. Plaintiffs were not provided a written notice of findings either before or after the MRA issued the Recall or summarily restricted and effectively suspended their licenses.

169. The most egregious violation of Plaintiffs' due process rights, however, was that they were denied the opportunity to contest the MRA's actions in front of a neutral decision maker. So far, the MRA has played the role of prosecutor, judge, jury, and the executioner of Plaintiffs' business. As explained above and alleged throughout this Complaint, the MRA and the named defendants specifically orchestrated their actions to avoid oversight from an administrative law

judge or court. The MRA and the named defendants were far from neutral in making its decisions regarding Plaintiffs.

170. As direct and proximate result of the MRA and named defendants' wrongful conduct, Plaintiffs were deprived of vested property and liberty interests without due process of law.

171. The named defendants are state actors.

172. The named defendants acted under color of state law.

173. The named defendants' actions alleged throughout this Complaint violated the due process clause of the Fourteenth Amendment of the United States Constitution.

174. The named defendants subjected or caused Plaintiffs to be deprived of their rights guaranteed under the due process clause of the Fourteenth Amendment to the United States Constitution.

175. As a direct and proximate result of the named defendants' wrongful conduct, Plaintiffs have suffered actual and nominal damages.

176. Plaintiffs are authorized by 42 USC 1983 to bring this suit against the named defendants for their wrongful conduct in violation of federal law.

177. Plaintiffs are authorized to recover their damages, along with its costs and attorney fees, under 42 USC 1988.

WHEREFORE, Plaintiffs respectfully request this Court enter a judgment in their favor and against the named defendants in an amount greater than \$25,000, along with their attorney fees as allowed by 42 USC 1988, and awarding Plaintiffs any other relief this Court deems just and proper.

COUNT II
42 USC 1983
VIOLATION OF PLAINTIFFS' SUBSTANTIVE DUE PROCESS RIGHTS UNDER THE
FOURTEENTH AMENDMENT OF THE UNITED STATES CONSTITUTION
(ALL DEFENDANTS)

178. Plaintiffs reassert and reallege the preceding paragraphs as if fully set forth herein.

179. The Fourteenth Amendment to the United States Constitution provides in Section 1 that no state shall “deprive any person of life, liberty, or property, without due process of law.” US Const, Amend XIV, § 1.

180. The due process clause of the United States Constitution protects a substantive right to due process, in addition to the above described procedural rights. The substantive component “protects against the arbitrary exercise of governmental power.” *Bonner v City of Brighton*, 495 Mich 209, 224; 848 NW2d 380 (2014).

181. Plaintiffs have a vested property interest in their licenses as a marijuana safety compliance facility to test cannabis products and a liberty interest to engage in their chosen profession and line of work.

182. In addition to violating Plaintiffs’ procedural due process rights, the named defendants have violated Plaintiffs’ substantive due process rights.

183. The MRA and the named defendants have wrongfully targeted Plaintiffs to further their political objective of equalizing market share of the cannabis testing industry between Plaintiffs and the competitors throughout the state. Upon information and belief, this was done to artificially dilute and cap Plaintiffs’ market share within the cannabis testing industry and/or effectively destroy Plaintiffs’ business operations thereby compelling Plaintiffs’ customers to seek to do business with its competitors.

184. As explained and alleged above, the MRA and the named defendants have wrongfully targeted Plaintiffs in retaliation for using the process outlined in the MMFLA and its administrative rules for filing an administrative complaint against the MRA for unnecessarily disrupting their business operations and their operations as a marijuana safety compliance facility.

185. As explained and alleged above, the MRA and the named defendants have wrongfully treated Plaintiffs as a collective entity instead of different business entities. Viridis Lansing is a separate and distinct entity with different ownership than Viridis Bay City. Contrary to the MRA's justification for including Viridis Bay City in the Recall, none of the samples of the October Audit were associated with Viridis Bay City. Each and every one of them was associated with Viridis Lansing. This means that the MRA instituted a Recall of cannabis products tested by Viridis Bay City without a failed audit test and based on the absence of incubator logs alone, which, the MRA, itself, has acknowledged, is insufficient to sustain a recall of this magnitude.

186. As explained and alleged above, the MRA and the named defendants wrongfully and arbitrarily included *all* cannabis products tested by Plaintiffs as part of its recall, including around 10% of those cannabis products that were *not* analyzed for aspergillus or other microbes by Plaintiffs. This means that the MRA recalled every cannabis product tested by Plaintiffs during a three-month period, even those samples that had no relation to the alleged deficiencies that formed the basis of the Recall.

187. The MRA's improper and wrongful conduct is arbitrary in the strictest sense.

188. The MRA's improper, arbitrary, and wrongful conduct shocks the conscience and has no place in ordered liberty.

189. As direct and proximate result of the MRA and named defendants' wrongful conduct, Plaintiffs were deprived of vested property and liberty interests without due process of law.

190. The named defendants are state actors.

191. The named defendants all acted under color of state law.

192. The named defendants' actions alleged throughout this Complaint violated the due process clause of the Fourteenth Amendment of the United States Constitution.

193. The named defendants subjected or caused Plaintiffs to be deprived of their rights guaranteed under the due process clause of the Fourteenth Amendment to the United States Constitution.

194. As a direct and proximate result of the named defendants' wrongful conduct, Plaintiffs have suffered actual and nominal damages.

195. Plaintiffs are authorized by 42 USC 1983 to bring this suit against the named defendants for their wrongful conduct in violation of federal law.

196. Plaintiffs are authorized to recover their damages, along with their costs and attorney fees, under 42 USC 1988.

WHEREFORE, Plaintiffs respectfully request this Court enter a judgment in their favor and against the named defendants in an amount greater than \$25,000, along with their attorney fees as allowed by 42 USC 1988, and awarding Plaintiffs any other relief this Court deems just and proper.

COUNT III
42 USC 1983
VIOLATION OF PLAINTIFFS' EQUAL PROTECTION RIGHTS UNDER THE
FOURTEENTH AMENDMENT OF THE UNITED STATES CONSTITUTION
(ALL DEFENDANTS)

197. Plaintiffs reassert and reallege the preceding paragraphs as if fully set forth herein.

198. The Fourteenth Amendment to the United States Constitution provides in Section 1 that no state shall "deny to any person within its jurisdiction the equal protection of the laws." US Const, Amend XIV, § 1.

199. Plaintiffs have been treated disparately from other similarly situated marijuana safety compliance facilities.

200. The MRA commenced a recall of all of Plaintiffs' tested cannabis products.

201. The MRA's purported reason for doing so was that it identified "inaccurate and/or unreliable results" related to Plaintiffs' testing. (**Exhibit M**).

202. As explained above and alleged throughout this Complaint, Plaintiffs did not deviate from their standard practice for microbial analysis and they accurately reported results relating to the cannabis products they tested.

203. Upon information and belief, no consumer has experienced any adverse effects associated with Plaintiffs' tested cannabis products, and the MRA and the named defendants failed to correct their assertions to the contrary even after they proved to be false.

204. Even if the MRA and the named defendants' positions were to be taken at face value, their actions are excessive, overbroad, and not in line with prior practice. In a prior case relating to Iron Laboratories, LLC, a marijuana safety compliance facility, the MRA discovered that Iron Laboratories was *actually* falsifying records in a way that directly affected safety. The MRA and Iron Laboratories entered a consent order that, among other things, temporarily suspended Iron Laboratories' license and fined it \$100,000. Despite Iron Laboratories *actually* falsifying its records involving toxic pesticide(s), the MRA *did not* immediately issue a recall of its tested cannabis products but instead waited two weeks later on August 30, 2019. Likewise, the MRA did not issue a recall related to the Spott where the MRA found that it had inaccurately reported potency results from May 3, 2019, to July 11, 2019. No recall was issued as a result. Documents relating to these enforcement actions are attached as **Exhibit P**.

205. Most glaringly, the MRA has not recalled cannabis products from *any* marijuana safety compliance facility that failed to keep logs for its incubators to perform microbial analysis.

206. Plaintiffs have not falsified their records and have accurately reported their test findings, but the MRA commenced the recall of all of its tested cannabis products.

207. There is no rational basis for the MRA's disparate treatment of Plaintiffs and from Iron Laboratories.

208. The MRA and the named defendants' conduct was intentional, arbitrary, and capricious.

209. The MRA and the named defendants' conduct was motivated by animus and ill-will towards Plaintiffs.

210. As a direct and proximate result of the MRA and the named defendants' wrongful conduct, Plaintiffs' equal protection rights were violated.

211. The named defendants are state actors.

212. The named defendants all acted under color of state law.

213. The named defendants' actions alleged throughout this Complaint violated the equal protection clause of the Fourteenth Amendment of the United States Constitution.

214. The named defendants subjected or caused Plaintiffs to be deprived of their rights guaranteed under the equal protection clause of the Fourteenth Amendment to the United States Constitution.

215. As a direct and proximate result of the named defendants' wrongful conduct, Plaintiffs have suffered actual and nominal damages.

216. Plaintiffs are authorized by 42 USC 1983 to bring this suit against the named defendants for their wrongful conduct in violation of federal law.

217. Plaintiffs are authorized to recover their damages, along with their costs and attorney fees, under 42 USC 1988.

WHEREFORE, Plaintiffs respectfully request this Court enter a judgment in their favor and against the named defendants in an amount greater than \$25,000, along with their attorney fees as allowed by 42 USC 1988, and awarding Plaintiffs any other relief this Court deems just and proper.

Respectfully submitted,

FOSTER, SWIFT, COLLINS & SMITH, P.C.
Counsel for Plaintiffs

Dated: February 18, 2022

By: David R. Russell (w/perm) Brandon M. H. Schumacher
David R. Russell (P68568)
Brandon M. H. Schumacher (P82930)

HONIGMAN, LLP
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Kevin M. Blair (P76927)

Complaint, Ex. A

Archived: Wednesday, December 22, 2021 9:22:08 AM
From: MCINTYRE Maria
Sent: Tue, 23 Nov 2021 19:06:10
To: Patterson, Claire (LARA) MRA-scf MILLS John
Subject: Re: Gene-up Aspergillus question
Importance: Normal
Sensitivity: None

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Hi Claire,

Let me check with John.

Maria

Get Outlook for iOS

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Tuesday, November 23, 2021 11:01:56 AM
To: MCINTYRE Maria <maria.mcintyre@biomerieux.com>; MRA-scf <MRA-scf@michigan.gov>; MILLS John <John.MILLS@biomerieux.com>
Subject: RE: Gene-up Aspergillus question

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Hi Maria,

I completely understand. Would you be able to meet 12-1?

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

(517) 230-2097
PattersonC8@michigan.gov
www.michigan.gov/MRA



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From: MCINTYRE Maria <maria.mcintyre@biomerieux.com>
Sent: Tuesday, November 23, 2021 1:59 PM
To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>; MRA-scf <MRA-scf@michigan.gov>; MILLS John <John.MILLS@biomerieux.com>
Subject: Re: Gene-up Aspergillus question

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Hello again,

Provided we do not currently have data to discuss would you be amenable to postponing our conversation until tomorrow?

Kind regards,
Maria

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From: MCINTYRE Maria <maria.mcintyre@biomerieux.com>
Sent: Tuesday, November 23, 2021 10:06:36 AM
To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>; MRA-scf <MRA-scf@michigan.gov>; MILLS John <John.MILLS@biomerieux.com>
Subject: Re: Gene-up Aspergillus question

Hi Claire,

I was advised data would be sent to both of us direct from Viridis. Thus far, no information has been received.

Maria

Get Outlook for iOS

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Tuesday, November 23, 2021 10:04:13 AM
To: MCINTYRE Maria <maria.mcintyre@biomerieux.com>; MRA-scf <MRA-scf@michigan.gov>; MILLS John <John.MILLS@biomerieux.com>
Subject: RE: Gene-up Aspergillus question

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Hi Maria,

Any updates from your end? Is there any way that I can provide you additional information to assist the licensee?

Claire Patterson

Manager, Scientific & Legal Section
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From: MCINTYRE Maria <maria.mcintyre@biomerieux.com>
Sent: Tuesday, November 23, 2021 11:45 AM
To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>; MRA-scf <MRA-scf@michigan.gov>; MILLS John <John.MILLS@biomerieux.com>
Subject: RE: Gene-up Aspergillus question

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Hi Claire,

Happy to support. Let's see how the timing works out for the files. If we need to adjust to the morning, are you and your team available tomorrow?

John- You're coming back from ETO for this conversation. What works best for your schedule?

Kind regards,
Maria

Maria McIntyre
425-275-8013

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Tuesday, November 23, 2021 8:16 AM
To: MCINTYRE Maria <maria.mcintyre@biomerieux.com>; MRA-scf <MRA-scf@michigan.gov>; MILLS John <John.MILLS@biomerieux.com>
Subject: RE: Gene-up Aspergillus question

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Maria,

That is great news! Thank you for providing that information. I am hoping we can get this resolved expediently and get the licensee back on track as soon as possible.

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

(517) 230-2097
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From: MCINTYRE Maria <maria.mcintyre@biomerieux.com>
Sent: Tuesday, November 23, 2021 11:14 AM
To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>; MRA-scf <MRA-scf@michigan.gov>; MILLS John <John.MILLS@biomerieux.com>
Subject: RE: Gene-up Aspergillus question

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Hello Claire,

Sounds good. Please know the lab is working to capture the data and send it over for our review. The raw data is essential to our conversation. After 2pm CST works for our schedules. If data is not received and reviewed in time for a discussion today, please share a couple options for Wednesday morning.

Thank you,
Maria

Maria McIntyre
425-275-8013

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Tuesday, November 23, 2021 5:38 AM
To: MCINTYRE Maria <maria.mcintyre@biomerieux.com>; MRA-scf <MRA-scf@michigan.gov>; MILLS John <John.MILLS@biomerieux.com>
Subject: RE: Gene-up Aspergillus question

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Hi Maria,

I am reaching out to them to see if they would like assistance.
That being said, what time would you be able to meet today?

Thank you again for your continued assistance.

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

(517) 230-2097
PattersonC8@michigan.gov
www.michigan.gov/MRA



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From: MCINTYRE Maria <maria.mcintyre@biomerieux.com>
Sent: Monday, November 22, 2021 9:54 PM
To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>; MRA-scf <MRA-scf@michigan.gov>; MILLS John <John.MILLS@biomerieux.com>
Subject: RE: Gene-up Aspergillus question

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Claire,

From my perspective it's easy to extract the files. Happy to ask the lab. Can you confirm the lab and any identification of samples to help with the request?

Maria

Maria McIntyre
425-275-8013

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Monday, November 22, 2021 5:48 PM
To: MCINTYRE Maria <maria.mcintyre@biomerieux.com>; MRA-scf <MRA-scf@michigan.gov>; MILLS John <John.MILLS@biomerieux.com>
Subject: RE: Gene-up Aspergillus question

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Maria,

Is it challenging for the lab to download these files? Previously it seemed that they thought it would be a significant challenge. Would you be able to provide

assistance if necessary?

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

(517) 230-2097
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From: MCINTYRE Maria <maria.mcintyre@biomerieux.com>
Sent: Monday, November 22, 2021 8:13 PM
To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>; MRA-scf <MRA-scf@michigan.gov>; MILLS John <John.MILLS@biomerieux.com>
Subject: RE: Gene-up Aspergillus question

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Hello Claire,

Certainly! The ixo files will be pivotal to our conversations. Let me know if you'd also like me to reach out to the lab.

Maria

Maria McIntyre
425-275-8013

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Monday, November 22, 2021 4:57 PM
To: MCINTYRE Maria <maria.mcintyre@biomerieux.com>; MRA-scf <MRA-scf@michigan.gov>; MILLS John <John.MILLS@biomerieux.com>
Subject: RE: Gene-up Aspergillus question

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Hi Maria,

Thank you so much for prioritizing this. We can share at least some information from the excel files themselves. I will work on obtaining the .ixo files as well.

Please let me know how I can set up a discussion and what works best for you.

Take care,

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

(517) 230-2097
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From: MCINTYRE Maria <maria.mcintyre@biomerieux.com>
Sent: Monday, November 22, 2021 5:11 PM
To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>; MRA-scf <MRA-scf@michigan.gov>; MILLS John <John.MILLS@biomerieux.com>
Subject: RE: Gene-up Aspergillus question

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Hello Claire,

The raw files will not be the excel files. They would be .ixc. Can you share the excel files? Is it possible to get the ixc files from the lab?

John and I will follow-up on options for a meeting tomorrow.

Thanks,
Maria

Maria McIntyre
425-275-8013

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Monday, November 22, 2021 1:06 PM
To: MCINTYRE Maria <maria.mcintyre@biomerieux.com>; MRA-scf <MRA-scf@michigan.gov>; MILLS John <John.MILLS@biomerieux.com>
Subject: RE: Gene-up Aspergillus question

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Hi Maria,

I really appreciate your response on this. I believe I do have the raw files from the instrument. These files are excel files that appear to be direct from the instrument itself. There are no amplification curves associated with these files.

I am able to connect tomorrow any time from 11:30am-3:30 pm. Let me know what works for you and I will send something through.

Thank you!

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

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From: MCINTYRE Maria <maria.mcintyre@biomerieux.com>

Sent: Monday, November 22, 2021 4:03 PM

To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>; MRA-scf <MRA-scf@michigan.gov>; MILLS John <John.MILLS@biomerieux.com>

Subject: RE: Gene-up Aspergillus question

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Hello Claire,

It's valuable to have the run files off the system to review the raw data. Is this something you have available? If not, I can check my files or ask the lab. To do so the lab information and product details would be needed. This information will fuel discussions. How is your schedule Tuesday to verbally connect?

Pardon the delayed response.

Thank you,
Maria

Maria McIntyre
425-275-8013

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>

Sent: Monday, November 22, 2021 5:44 AM

To: MRA-scf <MRA-scf@michigan.gov>; MILLS John <John.MILLS@biomerieux.com>; MCINTYRE Maria <maria.mcintyre@biomerieux.com>

Subject: RE: Gene-up Aspergillus question

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Good morning all,

Thank you for your continued support on the use of your platform.

I want to be clear when I say that we do not have any concerns about the platform itself, but we do have some questions and are requesting your expert advice on some data that we have.

This is obviously a time sensitive issue and probably best discussed in a meeting. Would you have some time today to discuss and hopefully provide some clarity?

Thank you both for your time and effort to keep this industry safe.

Take care,

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

(517) 230-2097
PattersonC8@michigan.gov
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From: MRA-scf <MRA-scf@michigan.gov>
Sent: Friday, November 19, 2021 4:26 PM
To: MILLS John <John.MILLS@biomerieux.com>
Cc: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Subject: Gene-up Aspergillus question

Hello John,

I hope you can help me out. I have attached a pic of a data output from a run. Am I to interpret that the positive control did not amplify from the output of the Cy5.5 channel indicating presumed absence. Thanks in advance for any help you can provide!

<div><div>INVISIBLE SENTINEL A BIOMERIEUX COMPANY Aspergillus Analysis Worksheet</div><div>Experiment ASP 22546-22596 Selected Filter: CY5.5</div></div>							
Include	Position	Sample Name	Cp	Max Floor	Max Floor (background)	RESULTS	Comments
TRUE	H2	22589	28.98	284.3417267	182.61892	Presumed Presence	IAC (Cy5.5)
TRUE	A3	22590	28.59	144.0601168	87.25287351	Presumed Presence	IAC (Cy5.5)
TRUE	B3	22591	28.49	131.2233684	82.80179039	Presumed Presence	IAC (Cy5.5)
TRUE	C3	22592	28.67	151.4117463	107.0533628	Presumed Presence	IAC (Cy5.5)
TRUE	D3	22593	28.54	170.1588268	123.0065786	Presumed Presence	IAC (Cy5.5)
TRUE	E3	22594	28.74	149.1271309	106.2257819	Presumed Presence	IAC (Cy5.5)
TRUE	F3	22595	28.57	122.4148812	90.76048916	Presumed Presence	IAC (Cy5.5)
TRUE	G3	22596	28.61	99.67663149	73.09920525	Presumed Presence	IAC (Cy5.5)
TRUE	H3	Pos	28.55	66.94407642	43.98187744	Presumed Absence	IAC (Cy5.5)
TRUE	A4	Neg		179.491447	5.858492516	Presumed Absence	IAC (Cy5.5)

Thank you,

Noah Rosenzweig, PhD
Laboratory Scientist Specialist
517-243-4395
Marijuana Regulatory Agency
P.O. Box 30205
Lansing MI 48909

RosenzweigN@michigan.gov
www.michigan.gov/MRA



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Data Review & Findings: Summary from bioMerieux/MRA Meeting

MCINTYRE Maria <maria.mcintyre@biomerieux.com>

Wed 1/12/2022 9:50 PM

To: Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>; Michael LaFramboise <mllaframboise@viridisgrp.com>

Cc: JOELSSON Adam <adamjoelsson@invisiblesentinel.com>; MILLS John <John.MILLS@biomerieux.com>; PASCAL Benjamin <bpascal@invisiblesentinel.com>; PASCAL Benjamin <ben.pascal@biomerieux.com>

Hello Michele, Greg, and Michael,

Here is a summary of findings for Viridis Labs verbally shared with the MRA on January 7, 2022–

There is no indication of errors in use or the assay itself.

Note that the GENE-UP data generated through “Qualitative Analysis” analysis settings in the OPEN SOFTWARE is considered raw data. The final determination of a given results is performed by the Aspergillus Excel Worksheet, which takes into account parameters such as Cp values and fluorescence values for each channel. Thus we can have an assigned Cp value but the sample is presumed absence (as noted for some results below).

4 patterns emerged in the requested data review as outlined below:

1. Cp values assigned in the gene UP open software, with a negative result reported in excel analysis tool. This is explained above.
2. Low IAC with strong traces in the controls – reported as undetermined in the excel analysis tool due to low IAC fluorescence. This can be related to competition of target vs IAC. Manual intervention to look at raw data is required for those wells to confirm strong trace in control target channel.
3. Low signal or missing IAC in negative target channels – this would indicate an issue with PCR efficiency and perhaps inhibition. Repeat analysis is recommended.
4. Plate map (also known as subset) identifies wells as having a sample when no tube is present. This will lead to no signal in all channels at that plate coordinate. Simply a plate set up issue. This can be remedied and modified after the run as needed.

As you review, please share if clarification or conversation is beneficial.

Kind regards,

Maria



Maria McIntyre

maria.mcintyre@biomerieux.com

Mobile: 425-275-8013

Customer Service 1-800-634-7656

www.biomerieux-USA.com

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Complaint, Ex. B



October 1, 2021

Gregoire Michaud
Viridis Laboratories
Lansing, MI

Dear Mr. Michaud,

We have received the assessor report and assessor deficiency report for the first year surveillance assessment of your organization that occurred on June 30, 2021.

Your corrective action response has been reviewed by A2LA staff and appears to be complete. Based upon the contents of the surveillance report and your corrective action response, your organization's management system, SOPs and technical capabilities appear to be in compliance with the accreditation requirements spelled out in **ISO/IEC 17025:2017**

This completes the information necessary to reaffirm your accreditation. Your accreditation is reaffirmed until August 31, 2022.

At this time, we would like to invite your attention to the next part of the accreditation cycle. Six months prior to your anniversary date, we will initiate the renewal accreditation process, which will require completing and uploading the required renewal forms, supporting documentation, and submitting payment. This step will initiate the complete renewal process, which includes an onsite assessment, submission of corrective action responses (if necessary), and the review and approval of the assessment records.

To learn more about the renewal of accreditation process or accreditation cycle, please contact your Accreditation Officer.

We would like to take this opportunity to say that we appreciate your participation in the leading national accreditation program and we welcome your feedback at any time. As always, if you have any questions regarding your accreditation, feel free to contact us.

Sincerely,

A handwritten signature in cursive script that reads 'Renee Delauter'.

Renee Delauter
Accreditation Officer, A2LA

RECEIVED by MCOC 11/22/2021 5:36:01 PM

Complaint, Ex. C

[illegible]

Complaint, Ex. D

STATE OF MICHIGAN
MICHIGAN OFFICE OF ADMINISTRATIVE HEARINGS AND RULES

VIRIDIS LABORATORIES, LLC,
a Michigan limited liability company, and
VIRIDIS NORTH, LLC,
a Michigan limited liability company,

Petitioners,

v.

MICHIGAN MARIJUANA REGULATORY
AGENCY, a Michigan state agency,

Respondent.

Docket No.: 21-029794

Case No.: SC-000009, SC-000014

Agency: Marijuana Regulatory Agency

Case Type: MMF Public Investigative
Hearings

Filing Type: Complaint by Licensee

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525 West Ottawa Street
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(517) 335-7569

**FIRST AMENDED COMPLAINT FOR UNNECESSARY DISRUPTION OF FACILITY
OPERATIONS**

Petitioners Viridis Laboratories, LLC and Viridis North, LLC (collectively “Petitioners”), by and through their attorneys, Foster, Swift, Collins & Smith, P.C. and Honigman, LLP, for their First Amended Complaint (“Complaint”) against Respondent Michigan Marijuana Regulatory Agency, state as follows:

PROLOGUE

Petitioners filed their initial complaint on October 25, 2021, alleging that certain of Respondent’s “investigative procedures” were “unnecessarily disruptive” of Petitioners’ facility operations. Respondent’s counsel inexplicably sat on Petitioners’ initial complaint for three weeks, despite multiple inquiries from Petitioners’ counsel. Respondent’s counsel eventually sent it to MOAHR weeks later, but only after Petitioners explicitly threatened to file a mandamus action requiring Respondent to process Petitioners’ complaint in accordance with MCL 333.27302(i). As discussed at the December 7, 2021 Prehearing Conference, (a) Petitioners’ initial complaint did not include certain details (the disclosure of which would only further “unnecessarily disrupt” Petitioners’ facility operations); and (b) even after Petitioners filed their initial complaint, Respondent has engaged in several more (and many ongoing) investigative procedures that have unnecessarily disrupted Petitioners’ facility operations. Thus, Petitioners requested, and this Tribunal granted, permission to file this First Amended Complaint.

As outlined in more detail below, it is largely beyond any reasonable dispute that Respondent’s investigative procedures have certainly *disrupted* Petitioners’ facility operations—including, without limitation, (a) tens of thousands of dollars incurred to satisfy Respondent’s arbitrary and endless list of demands for re-tests, video footage, source paperwork, etc.; (b) dozens of labor hours compiling information/documents requested by Respondent; and (c) being so unbelievably terrible at communicating that Petitioners spent considerable time and energy explaining/reminding Respondent that it had already approved Petitioners’ November SOP.

The only real remaining question, then, is whether all of Respondent's disruptions to Petitioners' facility operations were necessary. Petitioners respectfully contend that all of Respondent's investigatory procedures detailed herein unnecessarily disrupted (and are still unnecessarily disrupting) Petitioners' facility operations.

PARTIES, JURISDICTION, VENUE

1. Petitioner Viridis Laboratories, LLC ("Viridis Lansing") is a Michigan limited liability company formed under the laws of the State of Michigan and conducts business through a laboratory established in the City of Lansing, Ingham County, Michigan.

2. Petitioner Viridis North, LLC ("Viridis Bay City") is a Michigan limited liability company formed under the laws of the State of Michigan and conducts business through a laboratory established in Bay City, Bay County, Michigan.

3. Respondent Michigan Marijuana Regulatory Agency ("MRA") is a type I Michigan state agency established within LARA and is also charged with implementing, enforcing, licensing, and overseeing compliance with Michigan laws relating to marijuana.

4. The MRA (identified as the "Board" in the applicable statute and administrative rules) has the responsibility under the Michigan Medical Marijuana Facilities Licensing Act (MMFLA) (MCL 333.27101, *et seq.*) for "[r]eviewing and ruling on any complaint by a licensee regarding any investigative procedures of this state that are believed to be unnecessarily disruptive of marijuana facility operations." MCL 333.27302(i).

5. Under the MRA's administrative rules "a licensee may file a written complaint with the agency regarding any investigative procedures of this state he or she believes to be unnecessarily disruptive of the marijuana facility operations." MAC R. 420.706(1).

6. As explicitly framed by MCL 333.27302(i) and MAC R. 420.706(1), Petitioners' First Amended Complaint and these proceedings are necessarily limited to Petitioners' claims

that Respondent's "investigative procedures" have been and/or still are unnecessarily disrupting Petitioners' facility operations (and note, too, that "facility" is a term of art that means a marihuana operation that is licensed under the medical marihuana statute, the MMFLA).

7. The MRA may either (a) "delegate to a subcommittee of the agency to hear, review, or rule on" this Complaint or (b) "delegate authority to an administrative law judge" to have the merits adjudicated as a contested case. MAC R. 420.706(2) and (3). The MRA elected to send the matter to the Michigan Office of Administrative Hearings and Rules.

8. Consistent with the rules of notice pleading in Michigan, the purpose of this Amended Complaint is to put Respondent on notice of claims consistent with the allegations contained herein and is not meant to be an exhaustive identification of each and every actionable act or omission committed by Respondent.

9. It is unclear at this point whether the MRA has any established policies and procedures for addressing these types of complaints, or any guidance or rules on the parameters of that process. There are certain aspects of this Complaint and certain details that Viridis is deliberately not addressing in detail because they are confidential and any public dissemination of such information would cause even further unnecessary disruption of its business operations and operations as a marijuana safety compliance facility. Viridis respectfully submits that the existence of this Complaint should remain confidential (at least pending a determination on the merits). Viridis intends to file a forthcoming motion to seal, as appropriate, certain confidential materials.

GENERAL ALLEGATIONS

10. Viridis Lansing and Viridis Bay City are marijuana safety compliance facilities licensed by the MRA under the MMFLA and the Michigan Regulation and Taxation of

Marihuana Act (“MRTMA”) (MCL 333.27951, *et seq.*) to sample and test adult-use and medical cannabis products.

11. MRA regulates marijuana laboratories like Viridis through the MMFLA and MRTMA.

12. Viridis was founded by former Michigan State Police laboratory scientists with greater than 75 years combined experience working within a strictly regulated and nationally accredited forensic science industry, which included high volumes of marijuana testing.

13. Viridis Lansing received its license from the MRA to test medical marijuana on June 5, 2019, and its adult-use license on December 7, 2020.

14. Viridis Bay City received its license from the MRA to test medical marijuana on April 6, 2020, and its adult-use license on June 10, 2020.

15. The MRA requires marijuana safety compliance facilities to be accredited.

16. Viridis has accreditation ISO 17025:2017 by A2LA.

17. Viridis Lansing received accreditation on July 23, 2020.

18. Viridis Bay City received accreditation on February 4, 2021.

19. Viridis’ research and development is led by Michele Glinn, Ph.D, F-ABFT, the former program coordinator for the Michigan State Police crime labs.

20. Dr. Glinn is a well-respected toxicologist around the country and testifies as an expert witness for prosecutors in 40 to 50 cases a year.

21. The A2LA performed a full review of the validation and Standard Operating Procedures (SOP) of Viridis’ testing methods prior to its accreditation.

22. Licensed marijuana safety compliance facilities like Viridis are required to not only follow the requirements of the MMFLA and MRTMA, but also the rules promulgated by the MRA.

23. Under the MRA's Sampling and Testing Rules (the "Testing Rules"), a laboratory, which is defined to include marijuana safety compliance facilities like Viridis, must perform various tests on batches of marijuana products, including potency analysis. MAC R 420.301(m) and 305(3)(a).

24. The Testing Rules require that Viridis "use analytical testing methodologies for the required safety tests in subrule (3) of this rule that are validated by an independent third party and may be monitored on an ongoing basis by the agency or a third party. In the absence of reference to compendia or published methods, Appendix K of Official Methods of Analysis authored by the Association of Official Analytical Chemists must be published in full. The agency shall approve the validated methodology used by the laboratory and confirm that it produces scientifically accurate results for each safety test it conducts." MAC R. 402.305(2).

25. Part of the required testing, set forth in the Testing Rules, includes: "[p]otency analysis performed just as the marijuana product is without any corrective factor taken for moisture content that includes concentrations of the following: Tetrahydrocannabinol (THC)." MAC R. 402.305(3)(a). The purpose of potency analysis is to test, identify, and measure the levels of certain compounds within marijuana products for health and safety concerns, especially the concentrations of the psychoactive constituent tetrahydrocannabinol (THC) that gives marijuana its well-known effects.

26. The results of all potency tests completed by testing laboratories must be reported to the MRA's record keeping and tracking system-METRC. The MRA's record keeping and tracking system allows the MRA to review potency testing data at its discretion.

27. The MRA must necessarily rely on accrediting bodies such as the A2LA and scientific organizations like the AOAC for accreditation and method approvals because the MRA

scientists lack requisite scientific knowledge to govern the testing labs themselves, a fact that the MRA has previously acknowledged.

28. The MRA, through scientist Allyson Chirio, has historically and openly admitted that its scientists and employees have little to no experience or idea of what they are doing when it comes to regulatory oversight of marijuana facilities or testing methodologies. In fact, most recently, Ms. Chirio compared the MRA and its employees to infants and toddlers. Ms. Chirio stated that when the MRA took over the reins of regulating the cannabis industry in 2019 that it was like an infant (i.e., could barely function on its own and could not do anything for itself). Fast forward three years, Ms. Chirio compared the MRA to a toddler (i.e., can still barely function on its own but has learned some lessons from the past).

29. Labs undergo several extensive and rigorous processes before becoming accredited, licensed, and approved to perform tests.

30. Viridis implements and is known for employing state-of-the-art lab equipment and conducting accurate, correct, and reliable tests on cannabis products. Indeed, Viridis consistently finds ways to innovate its and other methodologies to create more accurate testing results. This has resulted in Viridis developing a patent-pending method for cannabis potency analysis (the “Viridis Method”). The Viridis Method is not set forth here because of its protected status as proprietary and trade secret information.

31. As Viridis’ regulatory body, the MRA has continuously monitored their testing methods, both in-person and via video, since Viridis Lansing and Viridis Bay City began operations. Over the course of years, the MRA has time and time again *observed* and *approved* Viridis’ testing methodologies after conducting audits and monitoring its methods.

32. Viridis has also consistently passed proficiency tests instituted by the MRA.

33. A proficiency test is a quarterly inter-laboratory comparison between competing marijuana safety compliance facilities. The purpose of the test is to verify that the labs are able to reach similar results when testing sample marijuana provided by the MRA.

34. Although the MRA requires marijuana safety compliance facilities to undergo proficiency testing, it does not publish the results of its testing. However, during a group question and answer session during one of the MRA's workshops in 2021, Executive Director Andrew Brisbo indicated that the MRA did "not see anything" out of the ordinary from a proficiency testing standpoint.

35. Viridis Lansing and Viridis Bay City have also successfully completed and passed external proficiency tests the previous two years as required annually by the MRA and the A2LA for accreditation purposes. These external proficiency tests are provided through Absolute Standards Inc., an approved, accredited third-party test provider recognized by the MRA.

36. Recently, in June 2021, Viridis Lansing successfully passed their annual accreditation surveillance assessment by the A2LA. This assessment included review of all of Petitioners' SOPs. (**Exhibit A**, A2LA Assessment).

37. Because Viridis provides accurate and reliable test results using the most up-to-date methods and equipment, the cannabis market, specifically growers and producers, have flocked to Viridis to test their products. By 2021, Viridis tested for between 60 to 70% of the cannabis market, meaning that 60 to 70% of all legal products on retail shelves have been tested by Petitioners.

38. The MRA took notice of Viridis' large percentage of market share in the cannabis industry.

39. Upon information and belief, there are only nineteen medical and seventeen adult-use marijuana safety compliance facility licensees in Michigan. Viridis Lansing and Viridis Bay

City hold two of the licenses, which means there are seventeen medical and fifteen adult-use non-Viridis related facilities that perform cannabis testing (the “competitors”). The competitors split the remaining 30 to 40% of the cannabis flower testing market.

40. Some of the competitors have taken issue with Viridis’ organic market share of the cannabis testing industry. Rather than out-competing Viridis, some of the other facilities have indicated that they want to remove Viridis from the market and industry entirely.

41. Several competitors have openly indicated to Viridis and the MRA during open, public calls that they wanted to see Viridis shut down and put out of business to open more market opportunities for themselves.

42. The MRA’s own internal political objective for the cannabis testing market is to ensure that all marijuana safety compliance facilities have a “fair share” of the testing market. In fact, during a recent webinar, Ms. Patterson indicated that the MRA’s political objective is to ensure that there is not too much of a market concentration in one particular lab. Ms. Patterson put on a slide, which was part of the webinar, that the MRA is asking marijuana safety compliance facilities to “work together,” that the MRA is seeking a “level playing field” between facilities, and takes issue with the fact that facilities are “not wanting to share proprietary methods.” (**Exhibit B**, Slide). Simply put, the MRA *does not* want marijuana safety compliance facilities to compete in an open market where the most efficient, up-to-date, and reliable lab wins. Instead, the MRA wants a homogenized group of mediocre labs where innovation will be stifled because of the MRA’s desire for labs to share proprietary information. While the MRA may want the cannabis testing industry to engage in a race to the bottom, that is not how open markets work.

43. Upon information and belief, based on its own stated policy goals and the vocal concerns of Viridis' competing marijuana safety compliance facilities, the MRA took issue with Viridis having a 60 to 70% market share of the cannabis testing industry.

44. The MRA has no inherent authority to regulate or cap a marijuana safety compliance facility's share of the cannabis testing market. However, as explained below, upon information and belief, there are strong, well-documented patterns that show that the MRA has weaponized its own administrative rules and processes to reach its desired goal. The MRA and its employees have engaged in a concerted effort and campaign to artificially dilute Viridis' market share in the industry or to remove Viridis from the cannabis testing industry altogether. In either scenario, the result will be the same: the competitors will obtain a larger piece of the cannabis testing pie.

45. The MRA started its campaign against Viridis by taking issue with the Viridis Method for potency analysis.

POTENCY

46. In January 2020, Viridis' first potency method via UHPLC-DAD was validated and approved.

47. Viridis continued to improve its UHPLC-DAD potency method by optimizing only the sample collection portion of the method after it was validated. An updated SOP was sent to the MRA on November 24, 2020 (the "November SOP") for continued monitoring. See **Exhibit C**.

48. The November SOP allows Viridis to more accurately report the true, maximum total THC potency in marijuana plant material as compared to Viridis' prior SOP. The November SOP results in enhanced accuracy in THC potency testing that protects consumers from being misinformed about the potency of their selected products. Respondent has claimed that inflating

potency would be a health and safety issue. First, Petitioners vehemently deny that the November SOP results in inflated potency results, but this Tribunal need not reach that issue to adjudicate these proceedings. The more important point is that Viridis strongly believes—and has repeatedly explained to Respondent to no avail—that Petitioners’ proprietary November SOP is uniquely capable of accurately testing potency, and that Petitioners’ competitors (who are mostly using more antiquated testing methods) are actually underreporting potency, which is a serious health and safety risk (e.g., if a medical patient knows their tolerance and consumes what she believes is cannabis containing 17% THC when the true THC content is actually 20%, that patient could have adverse affects attributable to that extra 3% of THC that she unwittingly ingested).

49. It is not unusual for Viridis’ potency method, outlined in the November SOP, to show that a sample’s total THC potency can reach levels exceeding 30%. Viridis’ method reaches those results because of the increased accuracy from its innovative, developed, and researched methods as compared to more antiquated methods.

50. Viridis’ average total THC potency results are around 21%, which is aligned with existing peer reviewed studies.

51. Around December 3, 2020, Viridis, the MRA, and representative members of the Michigan Coalition of Independent Cannabis Testing Laboratories (“MICIL”) attended a conference call where high potency results were discussed, along with the MRA’s continual requests for audits for any laboratory that posted potency testing results exceeding 29% (the “December 3 phone call”).

52. During the December 3 phone call, some competing laboratories voiced concerns to the MRA about “certain labs” reporting potency analyses exceeding 30% THC levels and the need to “audit” such results.

53. Since the December 3 phone call, the MRA has audited Viridis numerous times for potency test results in many forms.

54. Viridis has voiced its concerns to the MRA, especially relating to the fact that it may be the only lab being continually audited for high potency results.

55. The MRA represented that its requests for Viridis to audit its potency test results has nothing to do with complaints of other laboratories, and that its standard operating procedure “is and always has been to request re-analysis of potency samples exceeding ~27%.” The MRA then recommended that if Viridis has concerns about “the direction of conversations made by members of the association,” that Viridis contact them directly.

56. Since the December 3 phone call, the MRA has continued to request that Viridis audit its potency test results any time they exceed 27% THC levels. To date, the MRA has requested Viridis retest greater than 800 marijuana samples for potency results. This has resulted in lost revenue exceeding \$50,000, and an average of one day of lost productivity on a weekly basis, further and continually decreasing Viridis’ revenues.

57. On December 22, 2020, Viridis’ Lansing and Bay City laboratories were subject to virtual inspections by the MRA. During the inspections, the MRA observed Viridis testing under the November SOP in real time. The MRA’s inspection reports for the laboratories indicated that Viridis had passed the inspections. See **Exhibit D**.

58. In December 2020, Viridis sent the MRA all monthly and quarterly potency results for the November SOP showing remarkable consistency and reproducibility. In addition to the potency results, Viridis also submitted to the MRA peer reviewed literature on potency studies across the nation that closely aligned with Viridis’ data. See **Exhibit C**.

59. On February 5, 2021, Viridis Lansing was subject to an MRA review for a new microbial analytical method. The MRA's method review reports included an updated approval for the Viridis Method's potency analysis. See **Exhibit E**.

60. On March 19, 2021, Viridis Bay City received a method approval form from the MRA without any notation set forth in the potency section. See **Exhibit F**.

61. Viridis has since learned that following the MRA's inspection of its Lansing and Bay City facilities that its inspectors completed reports up to three months *after* the inspection had concluded. The MRA did not take immediate action to prevent Viridis from using the November SOP, or inform Viridis that it was taking the position that the November SOP was not approved.

62. On June 4, 2021, in preparation for annual accreditation assessments, the MRA sent Viridis Lansing copies of Viridis' December 2020 passing inspection reports.

63. On June 7, 2021, the MRA conducted a semi-annual inspection of Viridis Lansing, and on June 9, 2021, agents Noah Rosenzweig and Claire Patterson performed an on-site inspection that included a potency demonstration consistent with the November SOP. The MRA provided Viridis Lansing with a passing report and indicated that "[n]o deficiencies were found." See **Exhibit G**.

64. On June 8, 2021, the MRA also conducted a semi-annual inspection of Viridis Bay City via video that included a potency demonstration consistent with the November SOP. The MRA provided Viridis Bay City with a passing report, noting that "[n]o deficiencies were found." See **Exhibit H**.

65. On July 9, 2021, Viridis Lansing received another method approval report without any updates to the potency section. See **Exhibit I**.

66. On July 15, 2020, Viridis Bay City also received its second post-November-SOP method approval report that did not include any new notations to the potency section. See **Exhibit J**.

67. On August 2, 2021, MRA scientists, P. Fields and A. Chirio, performed a surprise visit to Viridis Lansing to observe its potency analysis method. Viridis Lansing performed the potency test as requested, again in conformance with the November SOP.

68. On August 10, 2021, Viridis Lansing received a third post-November-SOP method approval report, which again had no notations in the potency section. See **Exhibit K**.

69. Viridis Bay City received the same on August 25, 2021, receiving its third post-November-SOP method validation summary that also had no new notations regarding potency. See **Exhibit L**.

70. Since December 22, 2020, the MRA has observed, witnessed, and monitored Viridis perform the November SOP potency analysis four times (twice via video and twice in person).

71. The MRA has known since late 2020 that Viridis was using the November SOP, and the MRA has been monitoring Viridis perform the November SOP for over one full year.

72. On 13 separate occasions since the November SOP was implemented, the MRA has reviewed and approved Viridis' potency methodology.

73. Notwithstanding the fact that the November SOP has been validated and approved by the A2LA as required by MAC R. 420.305 ("Rule 305") and has been continuously monitored by the MRA, the MRA now contends that Viridis' latest approved potency SOP is the one that the MRA approved on July 8, 2020. See **Exhibit M**.

74. On August 25, 2021, the MRA filed three complaints against Viridis Lansing and three complaints against Viridis Bay City (collectively the "Complaints").

75. The Complaints will not be detailed here because of their recklessly inaccurate and salacious accusations that would only further the unnecessary disruption of Viridis' facility operations.

76. The Complaints will also not be detailed here because they contained confidential and proprietary information that is not subject to disclosure pursuant to MCL 333.27302(m)(i), 27401(3), and 27959(7).

77. The Complaints rely on the MRA's inaccurate allegations that it never received, monitored, and approved the November SOP.

78. It is impossibly arbitrary and capricious, and unnecessarily disruptive of Viridis' facility operations, for the MRA to disavow the November SOP after monitoring and approving it 13 times in less than one year.

79. The MRA's actions are not based on scientific justifications or fact.

80. The MRA's actions have directly interfered with and disrupted Viridis' business operations and its operations as a marijuana safety compliance facility.

81. On September 7, 2021, in response to the Complaints, Viridis, through counsel, requested a compliance conference as provided by MAC R. 420.740(1) and a contested case hearing as provided by MCL 333.27407(4), 27947(1)(c), and MAC R. 420.704(2).

82. Viridis also requested a copy of the MRA's file related to the Complaints as contemplated by MCL 24.274(2).

83. On September 7, 2021, for the first time, Claire Patterson from the MRA sent an email to Viridis seeking a verification of the SOP that Viridis is currently using. In Ms. Patterson's email, she stated "we have two dates on record for method updates, one in 2020 and one 2021. The one dated for 2021 was denied for use, so I want to make sure that the

appropriate method is being used until the appropriate validations are provided to the agency for approval.”

84. The MRA had observed the November SOP four times and approved it 13 times by the time Claire Patterson sent the September 7, 2021, email.

85. On September 7, 2021, one of Viridis’ members, Greg Michaud, responded asking for clarification as to the 2020 and 2021 SOP’s that Ms. Patterson was referencing.

86. Around the same time, on September 7, 2021, the Marijuana Enforcement Tracking Reporting & Compliance (i.e., METRC) indicated to Viridis via email that the MRA had flagged several of its analyzed samples as needing re-tests because of high potency results. Among other things, METRC personnel requested that Viridis indicate the SOP used to prepare the potency reports and the date of the last update to the method.

87. Viridis responded to METRC by indicating that the November SOP was used and that it received approval from the MRA in December 2020.

88. The MRA responded that the November SOP was not approved and that the latest approved SOP it has on record relates to a SOP submitted in July 2020.

89. Viridis’ samples cannot be retested, and more important retested accurately, until the MRA gives METRC approval to accept re-tests based on the November SOP. Until METRC receives the MRA’s approval, Viridis’ customers’ products cannot be released into the market and are effectively left indefinitely in queue.

90. The MRA’s attempt to retroactively disapprove the November SOP through METRC has unnecessarily and unreasonably disrupted Viridis’ business as it has effectively stopped it from doing business through the METRC system for samples showing high potency results.

91. On September 8, 2021, Ms. Patterson responded back to Greg Michaud attaching SOP's that did not include the November SOP.

92. As a result of the MRA's attempt to disavow its approval of the November SOP, counsel for Viridis immediately attempted to facilitate discussions with the MRA related to the November SOP and why Ms. Patterson was representing that the MRA did not have the November SOP.

93. On Monday, September 13, 2021, counsel for Viridis had a phone call with Jessica Fox from the MRA to discuss the Complaints. Viridis again voiced its concerns about the Complaints' inaccurate accusations, again requested an expedited compliance conference, and again requested a copy of the MRA's file.

94. Ms. Fox represented that the MRA would turn over its file and asked counsel to follow up with an email again seeking the file.

95. On September 13, 2021, Viridis, through counsel, again asked for a copy of the file via an email to the MRA.

96. On September 14, 2021, Viridis' counsel received notice that the compliance conference was scheduled for November 30, 2021.

97. On September 14, 2021, the MRA sent Viridis a Request for Video for Viridis Lansing and Viridis Bay City's previous 30 days of operation. The MRA gave Viridis two days in order to turn over hundreds of hours of requested video from a significant number of video cameras. The MRA later agreed to provide more manageable parameters for the request, but at an additional cost of \$5,000 to Viridis.

98. On September 23, 2021, counsel for Viridis had a follow-up phone call with Jessica Fox seeking to further clarify the issues about the November SOP.

99. On September 28, 2021, the MRA sent Viridis a Request for Information, seeking foreign matter work logs for Viridis Lansing and Viridis Bay City's previous six months of operations and any error logs for "the Tempo," specifically relating to error code "c19." The MRA gave Viridis Lansing a deadline of close of business October 1, 2021, a total of three days to comply.

100. Viridis Lansing responded to the MRA's Request for Information by indicating that a request of that magnitude would "negatively impact our daily operations for approximately 7-8 working days" in light of the fact that Viridis would have to go through greater than 1,800 document bundles manually to recover the requested documents.

101. On October 1, 2021, without ever providing a copy of the MRA's file or any of Viridis' requested information, Jessica Fox sent an email to Viridis' counsel that the file had been turned over to the Attorney General's office and the MRA refused to have any further communication with Viridis' counsel.

102. There is no reason for the MRA to continue requesting Viridis reanalyze its potency results using the November SOP. This is supported by the MRA's own random proficiency testing.

103. Viridis used the November SOP to complete one or all of the MRA's proficiency tests.

104. To date, Viridis has participated in three proficiency tests required by the MRA. The MRA has not raised any issues with its submitted potency proficiency results. This means that the November SOP is an appropriate method of potency analysis based on the MRA's own testing and data.

105. The MRA's decision to retroactively disapprove the November SOP is not meant to protect the public. The MRA is, in essence, requiring Viridis to complete potency testing

through antiquated and less-accurate methods of analysis. In other words, the true levels of THC in the marijuana products being tested *will not* be as accurate as if the November SOP was used.

106. The MRA mandates that all laboratories use “analytical testing methodologies . . . that are validated by an independent third party and may be monitored on an ongoing basis by the agency or a third party” to complete the testing required by the Testing Rules. MAC R. 420.305(2). Rule 305 further provides that the MRA “shall approve the validated methodology used by the laboratory and confirm that it produces scientifically accurate results for each safety test it conducts.” *Id.* In the absence of reference to compendia or published methods, Rule 305 defaults to Appendix K of Official Methods of Analysis authored by the Association of Official Analytical Chemists. *Id.*

107. Neither Rule 305 nor any other administrative rule promulgated by the MRA provides what criteria it will use to determine whether a testing method is “validated.”

108. The MRA admits that there is no criteria for determining what methods are “validated” in a guidance memo where it states “a standard method for the quantitative analysis of cannabinoids [(i.e., THC)] has not yet been published.”¹ In other words, even though there is no standard method for the quantitative analysis of THC (i.e., potency testing), the MRA has attempted to retroactively disapprove the November SOP.

109. In June 2021, Viridis Lansing successfully passed their annual accreditation surveillance assessment by the A2LA. This assessment included the review of all SOPs, including the November SOP potency method. See **Exhibit N**.

¹ *Sampling and Testing Technical Guidance for Marijuana Products (Revised July 1, 2021)*, Michigan Marijuana Regulatory Agency, p. 15, https://www.michigan.gov/documents/mra/Sampling_and_Testing-Technical_Guidance_for_Marijuana_Products_694124_7.pdf.

110. The MRA cannot arbitrarily withdraw or refuse to approve a potency analysis method.

111. The MRA has since continued to escalate and complicate these issues by unnecessarily and directly interfering with Viridis' day-to-day operations through overreaching investigatory requests, some of which are contrary to its own regulations.

112. On October 12, 2021, MRA agent Claire Patterson sent an email to Viridis with investigation requests for outstanding and "*current*, on-going investigations."

113. The investigation requests from Ms. Patterson included 18 requests, consisting in part, of the following:

Currently Outstanding Investigation Requests

- a. Video footage of Viridis Bay City;
- b. Potency prep sheets for 6 specific samples;
- c. Follow up request for calculation sheet for mold, pests and powdery mildew along with specific questions related to those calculations;
- d. Request for Method analysis added to Certificate of Analysis;

Currently Outstanding Method /Validation Requests

- e. The request states that in order to approve any updates made to the potency method (SOP LOM-7.1a Cannabinoid Analysis by HPLC-DAD), that is any updates that alter the method from the reference method, we require a complete validation to AOAC Appendix K. This also includes updates to the prep method that was approved by the MRA in January 2020.²

² This request is directly related to the 6 complaints filed by the MRA on August 25, 2021, set forth in paragraph 54 above.

- i. Submit a validation report, with an appropriate experimentation, statistical power, statistical design (e.g. RCBD or CRBD) and statistical analyses (e.g. ANOVA, Turkey HSD or Fisher LSD) to enable acceptance of the null hypothesis (H_a).
 - ii. Alternatively, the laboratory may opt to run the reference method. If the laboratory opts to return to the reference method, they must also adhere to the appropriate SMPR's for the Potency.
- f. Microbial Testing approval request for SOP matrix expansion;
 - g. Requirement for additional information about Terpenoid Analysis;
 - h. Request for information related to a requested Chemical Residue SOP matrix expansion;

New Investigation Requests

- i. Request for Initial Demonstration of Capability (IDOC) for all technicians performing foreign matter analysis;
 - i. The documents(s) used to train staff about identifying foreign matter as well as how to calculate foreign matter for the entire sample;
- j. Request for photos of samples which contain foreign matter detected in flower samples for the last 6 months;
- k. Request for all calculations performed for foreign matter for that past 30 days that determine whether a sample is pass or fail;
- l. Request for information about two specific METRC samples asking for amount left in storage;
- m. Request for the SOP currently used by staff to complete foreign matter analysis;

- n. Request for an instrument read-out of all tests performed on both the gene-up and aria platforms within the past 3 months;
- o. Request for Incubation logs for all *Aspergillus* tests performed in the month of September;
- p. A complete list of all currently employed methods, the date of the last update, and the date that the method was approved by the MRA, as well a copy of all current SOPs currently in use;
- q. A copy of all internal audits performed in 2020-2021;
- r. A daily schedule of when analyses are typically performed, or if ongoing throughout the day, please let us know;

- 1. In addition, a request for several dates and time during the next two weeks for both Viridis locations when all technicians/analysts can be available for interview.

A copy of the above requests is attached as **Exhibit O**.

114. On October 19, 2021, Viridis received a returned ticket from METRC stating, “per the MRA, ‘Please ask for the equipment maintenance log of all incubators along with least temperature verification performed by an outside company.’” The MRA has *never* requested this information in the past and is now arbitrarily requesting Viridis perform additional tests by outside vendors without explanation as to why the test is being performed.

115. Subsequent to receiving the above requests from the MRA, on October 21, 2021, the MRA indicated in an email to Viridis that it intended to conduct full-day audits at both Viridis Lansing and Viridis Bay City. The MRA intended to “perform audits of the methods and procedures in real time” and to ask “questions related to the method and SOP.” A copy of the MRA’s email exchange and proposed schedules is attached as **Exhibit P**.

116. Viridis Lansing followed up on the MRA's email request and inquired if the audits were for "quality assurance" or "post-complaint" investigation. The MRA responded that it would be "quality assurance audits, post-complaint audits, and investigatory audits."

117. Some or all of the MRA's "audits" described above are contrary to law.

118. Under MAC R. 792.10117, post-complaint fact finding (discovery) (i.e., the MRA's proposed post-complaint and investigatory audits) may only be approved by an administrative law judge. The MRA *has not* obtained such approval and, therefore, is acting contrary to its own regulations and Michigan law.

119. MAC R. 420.808(1) also reflects the unremarkable principle that investigations necessarily occur before, not after a complaint is issued. The MRA's attempts to conduct post-complaint discovery here are clearly improper. Viridis has already informed the MRA and its counsel that Viridis will not oppose any requests for reasonable discovery. However, the MRA has not asked the ALJ to allow for and decide the proper scope of discovery. In other words, Viridis has already articulated its concerns and objections to the MRA and its counsel, and rather than promptly sending Petitioners' initial complaint to MOAHR, it appears that the MRA deliberately tried to circumvent this Tribunal's authority to manage discovery, if any.

120. Based on the MRA's wrongful conduct outlined above, Viridis filed its original Complaint for Unnecessary Disruption of Facility Operations against the MRA on October 25, 2021. (**Exhibit Q**, Complaint, absent exhibits). Viridis filed its Complaint based on the proper processes and channels to address the MRA's conduct. However, unbeknownst to Viridis, its mere use of process would set off a chain-reaction wherein the MRA would take every effort to destroy Viridis' business operations through calculated, excessive, arbitrary, capricious, and ever changing investigatory practices.

121. On October 25, 2021, the MRA escalated its campaign against Viridis by gratuitously revealing to Viridis' competitors that it was under investigation via email. In that email, the MRA directed that 10 of Viridis Lansing's previously tested samples were to be retested as part of the audit by other marijuana safety compliance facilities for microbial testing, including aspergillus, total yeast and mold, foreign matter, and pesticides. The MRA "randomly" selected several of the competitors for the audit testing. Copies of the sample audit notices from METRC are attached as **Exhibit R**. The MRA did not require any sample from Viridis Bay City to be retested as part of this audit request.

122. The MRA does not have its own safety compliance facility, so it selected "random" testing facilities to re-test Viridis' previously tested cannabis products.

123. Several of the marijuana safety compliance facilities that the MRA "randomly" selected to perform audits of Viridis Lansing's samples are the same competitors that have consistently complained about Petitioners, as a whole, having a large portion of the market for cannabis testing and have publically stated that they want to see Petitioners put out of business.

124. Unsurprisingly, 4 of the 10 samples were consistent with Viridis Lansing's prior results.

125. 6 out of 10 of Viridis Lansing's previously tested samples that were sent to its competing labs as part of the October Audit were ultimately "failed." The MRA received or knew of 90% of these results by November 1, 2021, and the remaining results were provided to the MRA by November 5, 2021. However, as explained below, they did not express any concern or take any action until November 15, 2021.

126. On October 26 and 27, 2021, the MRA, through its employees Noah Rosenzweig, Patrice Fields, Allyson Chirio, and Claire Patterson, conducted its on-site "audits" at Viridis

Lansing and Viridis Bay City’s respective facilities (the “October Audits”). At the time of the October Audits, the MRA knew and had received a copy of the initial complaint.

127. During the October Audits, the MRA observed Viridis perform numerous tests on cannabis samples, including potency and microbial analysis for aspergillus, total yeast and mold, foreign matter, and pesticides.

128. The MRA originally scheduled the October Audits at Viridis Lansing and Viridis Bay City to be all-day observations. Instead, the MRA stayed at each facility for only two hours. At no time did the MRA or any of its employees indicate to Viridis or its employees that they observed an error or deviation that was a risk to public health or safety. In other words, the MRA did not leave after just a fraction of the scheduled time because they saw something concerning that needed to be addressed immediately—i.e., as noted below, the MRA did not even share its summary of the October Audits until three weeks later. The MRA also did not leave after just a fraction of the scheduled time because Petitioners were somehow inhibiting their inspection; rather, Petitioners blocked out their schedules and had planned to give the MRA inspectors their undivided attention all day. The MRA personnel had free reign within both laboratories to walk around and observe anything they wanted to observe and talk to any Viridis personnel they wanted to speak with.

129. At the end of the October 25, 2021 visit, the MRA indicated that it would provide a written summary of its findings and give Viridis Lansing an opportunity to respond (much like a compliance audit).

130. At the end of the October 26, 2021, visit at Viridis Bay City, the MRA again indicated that it would provide a written summary of its findings “soon” and Viridis Bay City would have an opportunity to respond.

131. On November 15, 2021, almost three weeks *after* the MRA completed the October Audits, it released and forwarded to Viridis its Onsite Audit Findings (collectively the “October Audit Findings”). (**Exhibit S**, Viridis Lansing’s Onsite Audit Findings; **Exhibit T**, Viridis Bay City’s Onsite Audit Findings).

132. Unlike the MRA’s prior practice, the October Audit Findings did not provide Viridis any opportunity to respond to the alleged deficiencies in its practices or testing procedures. Instead, on the same day, the MRA, during a Teams phone call, notified Viridis that it was going to notice a recall of all of Viridis’ previously tested cannabis products that were tested between August 10, 2021, and November 16, 2021.³

133. Ever since the MRA first mentioned the possibility of a recall, the MRA has articulated (via phone and/or Teams or Zoom, but still not in writing as required under the rules) only two bases for the recall. First, the MRA asserted that Viridis had failed to keep a log book showing that they had kept the samples tested for aspergillus and other microbials in its bioMerieux incubator (a machine required for the test) for 24 to 48 hours. After Viridis explained, and the MRA acknowledged, that such logs are not required by statute, rule, any informal MRA guidance, or Viridis’ SOPs, at that point the MRA shifted and said the recall was warranted because it asserted that Viridis Lansing’s 6 out of 10 retested and “failed” samples evidenced issues with the accuracy of Viridis Lansing’s prior microbial analysis tests, specifically for aspergillus.

³ To be clear, the MRA’s decision to issue the recall, itself, was not an “investigative procedure” and is not part of this Amended Complaint; the legality of that recall is one of the issues in dispute in the pending Court of Claims case (No. 21-000219-MB). The recall is mentioned and discussed in this Amended Complaint only for context—especially as to the MRA’s numerous “investigative procedures” that occurred before, during, and after the actual recall that were unnecessarily disruptive of Petitioners’ facility operations.

134. Neither of two grounds the MRA provided to Viridis for the recall are supported by any applicable law or rule. In fact, Viridis never deviated from the method accredited by A2LA and the SOP approved by the MRA and which it observed Viridis perform numerous times over the course of two years. Not once did the MRA comment on the lack of an incubator log before October 25, 2021.

135. The MRA proposed to issue the recall for between August 10, 2021, and November 16, 2021, which is completely arbitrary. This was pointed out first in a phone call with the MRA, on November 16, 2021. Viridis explained that it had never kept log books since its inception, and if that was the basis for a recall, then the proposed recall would necessarily include all microbial tests ever completed by every marijuana safety compliance facility within the industry. During that conversation, Desmond Mitchell, the MRA's Operations Director, told Viridis that he was "doing them a solid" by not making the recall much broader in scope.

136. The fact that the MRA knew and approved Viridis' procedure for microbial testing, including aspergillus, which has never included keeping logs for the incubator, shows that this recall has nothing to do with public health and safety.

137. The fact that the MRA sat on this information for three weeks and did nothing shows that this recall has nothing to do with public health and safety.

138. Rather, upon information and belief, the timing of the recall was intended to impose maximum damage, as it came just before the busy Thanksgiving holiday and so-called "Green Wednesday," which is among the busiest sales days of the year for cannabis retail locations.⁴

⁴ <https://www.forbes.com/sites/lindseybartlett/2020/11/30/cannabis-sales-in-the-us-soar-on-green-wednesday/?sh=10f8aa27625d>

139. As stated above, the MRA continuously monitors Viridis and has been fully aware of its SOP, which does not include keeping log books.

140. The MRA has approved this method and the A2LA has done an accreditation of the method, which is pending approval.

141. In response to an email questioning the scope of the proposed recall on November 17, 2021, Mr. Mitchell stated “[t]he investigation is still ongoing. As part of that investigation, we’ll determine if the recall should be expanded as you’ve indicated [*this was in response to Viridis counsel pointing out that Viridis has never kept log books and the MRA has known that since it first started testing*]. If it does, we expand the recall. However, as Kevin [Blair] has pointed out before this is a public health and safety issue and we need to act on this as soon as possible.” (**Exhibit U**, Email Correspondence between MRA and Viridis’ Counsel).

142. Upon information and belief, many—if not all—marijuana safety compliance facilities have not or do not keep log books for their incubators for microbial analysis, which the MRA has knowledge of but has never issued any recall related to this failure.

143. The MRA’s position is not supported by the evidence before it, and was specifically designed to set Viridis up to fail.

144. Over the course of several days, the MRA, through its various representatives, and Viridis, through their counsel, corresponded about the proposed recall and the grounds for said recall. Copies of those correspondences are attached as **Exhibit U**. The most egregious parts of the MRA’s communications with Viridis are highlighted in the body of this Amended Complaint.

145. In addition to the written communications attached as **Exhibit U**, the MRA also had numerous telephone conversations with Viridis’ counsel. The MRA, through Mr. Mitchell indicated that a lack of a log book, on its own, would not warrant a recall. He indicated that the

MRA was making the recall because of the alleged deficiencies in Viridis Lansing's 10 samples that were retested by the competitors.

146. Viridis challenged the MRA's reliance and means of retesting Viridis Lansing's 10 samples as part of the October Audits. By using the competitors, especially those who have publically indicated they desire to see Petitioners shutter their doors, the MRA placed Petitioners on the path to failure. (**Exhibit U**).

147. Viridis also challenged the MRA's reliance on the absence of log books. A marijuana safety compliance facility is *not* required by statute, administrative rule, or even the MRA's own technical guidance to keep a log book of hours in an incubator or temperature. Nor does the AOAC (the organization referenced and relied upon by the MRA for scientific guidance) or the incubator's manufacturer, bioMerieuxm, require such logs. Nor does Viridis' validated, accredited, and MRA-approved SOP.

148. The MRA observed Viridis perform microbial analysis testing, including for aspergillus, for over two years and has *never* raised concerns of Petitioners not having a log book for its incubation process. It curiously now takes issue with this fact. In July 2021, the MRA conducted a proficiency test of Viridis Lansing and approved all 60 aspergillus samples tested by Viridis Lansing using the exact procedure that the MRA now claims is unreliable. (**Exhibit N**).

149. Viridis Bay City also challenged the breadth of the MRA's proposed recall because the MRA did *not* request that it send *any* samples for audit. Put simply, the only grounds the MRA had for recalling Viridis Bay City's tested products was the lack of log books, which the MRA consistently indicated was not sufficient, on its own, to warrant a recall. Yet, the MRA issued the recall for Viridis Bay City anyway, merely because it has the word "Viridis" in its name. Tellingly, the Court of Claims *agreed* with Viridis on this point and preliminarily *enjoined* the MRA from enforcing the recall against Viridis Bay City. (**Exhibit V**, Opinion and Order).

150. Viridis also challenged the MRA's proposed recall on the grounds that it was overbroad because it included samples (around 10% of the cannabis products covered by the recall) that were *not* tested for microbials and would have nothing to do with the alleged deficiencies identified in the October Audits.

151. When the MRA would not change its position on the recall based on Viridis' own correspondence, Viridis contacted representatives from the AOAC and bioMerieux the vendor of the aspergillus testing platform known as GeneUp, to learn their positions on the matter, especially as to the MRA's use of several of the competitors to perform the sample audits.

152. Patrick Bird, a widely respected consultant from the AOAC⁵, that the MRA routinely relies on for expertise, concluded that the MRA's methodology was scientifically flawed and would not be sufficient to support a recall. In his email to the MRA on November 17, 2021, trying to educate the MRA on why a recall would be inappropriate stating the following:

1. AOAC INTERNATIONAL's role in the cannabis industry is to develop standards and guidance to allow alternative methods to be certified through one of its conformity assessment programs. The certification of the method demonstrates its fit for purpose for use in that industry if the method is performed as written in the validation guidelines. AOAC is not involved in laboratory assessment and/or accreditation.
2. Determining if a laboratory is performing a method correctly falls on the accreditation organization that issues the ISO 17025 certificate. If a method is certified during the accreditation it demonstrates that the laboratory is competent to run that method. The MRA's decision to recall these products due to the lack of traceability of the incubation logs indicates an issue with the accreditation process and not AOAC's certification. In this instance, the lab has demonstrated they can competently perform the method through their accreditation, although we all acknowledge there is a gap in the data collection process that fully supports this.

⁵ The MRA relies on the AOAC as part of its Testing Rules, which require licensees to follow Appendix K of the AOAC. MAC R. 420.305(3).

3. **The additional testing of materials at other labs is not something that I believe supports a recall as there are many factors in play that may have lead to the different results (same batch but different test portions analyzed, time gaps in analysis from one lab to another, etc).**

(Exhibit U).

153. Maria McIntyre, from bioMerieux,⁶ mirrored the consultant from the AOAC's position as well. She indicated that the methodology used by the MRA was not able to produce scientifically accurate or reliable results and that, in essence, the only thing that the MRA was basing its recall on was the absence of log books. In an email to MRA, on November 17, 2021, she also tried to educate the MRA on why a recall based on its reasoning was flawed:

1. Methods utilized have AOAC approval. This data collection usually includes robustness data that may or may not be a change in temperature. Please know, we are working to confirm if this data is available from the work for AOAC. This may take time to capture as I am collaborating with John Mills- Scientific Affairs Manager and Dr. Ron Johnson- former AOAC President.
2. ISO 17025 accreditation impacts the discussion as ISO sets the benchmark for the quality standards within accredited laboratories. If a recall is generated under these circumstances it's a reflection of a gap in ISO accreditation and does not relate to AOAC or the method itself. The lab has completed training on the method reflected in the training certificates and demonstrated via the ISO 17025 accreditation process.
3. When there is uncertainty in results either retesting or confirmation testing generally holds greater value than a multi-lab study. In such a study, there are many variable in the equation leading to variability.
4. The iso files have been reviewed and the assay appears to be running properly. The files have been transferred to the R&D team who created this assay for a 2nd opinion and to determine if other areas require addressing.

(Exhibit U).

154. Viridis tried to reason and educate with the MRA up until the very last minute. Not only did the two most reliable subject matter experts opine that the recall was inappropriate

⁶ bioMerieux's incubator is the same platform used by all of the labs that the MRA sent the samples to that tested Viridis' samples. bioMerieux has more expertise on their platform and the reliability of these tests than anyone else.

based on these flawed tests, Viridis offered for the MRA to review the video evidence that it already had in its possession and to supplement that with further video so that the MRA could confirm that Viridis had properly tested for microbial contamination, including aspergillus, for the required time. The MRA refused to look at the video evidence.

155. Notwithstanding irrefutable evidence that the MRA's rationale for a recall was not based in science, the MRA refused to budge and issued the recall bulletin on November 17, 2021. (**Exhibit W**, Recall Bulletin). The MRA further indicated in the recall bulletin that an "MRA investigation is still on-going."

156. Because Viridis tested for 60 to 70% of the cannabis industry, that means the recall covers 60 to 70% of all cannabis products in the market. The MRA's recall has created chaos and panic within the cannabis industry. Growers, producers, and retailers are scrambling trying to get their products back on the market. Smaller growers and retailers have voiced their concerns over the lack of product and indicated to the MRA, Viridis, and others in the cannabis industry that they will not be able to survive because of the product and cash flow interruptions caused by the recall.

157. As previously stated, the recall is overbroad. It covers not only all of Viridis' previously tested products, including products that were tested for items unrelated to microbials analysis and were thus unrelated to the MRA's concerns, but also products from Viridis Bay City, which, again, did not provide *any* samples for audit because they were not requested by the MRA.

158. The MRA's recall included over 64,000 lbs. of flower totaling over \$229 million using the average retail price per lbs. between August 10, 2021, and November 16, 2021.

159. Over 10% of the recalled cannabis products were not tested for microbial analysis.

160. The MRA's recall is improper in both scope and substance.

161. Upon information and belief and reasonable inference, the MRA issued the recall, at least in part, as retaliation for Viridis filing the Complaint attached as **Exhibit Q**.

162. Many of Viridis' customers learned about details of the recall prior to it being issued on November 17, 2021 (in fact, some customers knew of the recall as early as November 8, 2021, a week before *Viridis* knew of the recall), which upon information and belief, was leaked from within the MRA. Indeed, upon information and belief, the competitors were celebrating the recall prior to November 17, 2021.

POST-RECALL DE FACTO SUSPENSION

163. To add insult to injury, after the MRA issued the recall notice, it indicated to Viridis in an email that because it had "corrected" the log book issue by implementing said process into its microbial testing process, that it was approved to begin re-commencing microbial analysis testing. An email evidencing this fact is attached as **Exhibit U**.

164. The MRA then *changed its position* in less than 24 hours and indicated that Viridis could only test for aspergillus. (**Exhibit U**). The MRA then changed its position *again* by informing Viridis' customers, without informing Viridis, that Viridis cannot perform *any microbial testing* as a result of the recall.

165. The MRA's recall notice has put growers, producers, retailers, and others connected to Viridis in chaos because of its breadth and unexpectedness. The recall, by its terms, allows those affected by it to have the product retested for microbial analysis.

166. Several of Viridis' existing customers called the MRA to verify that Viridis was able to perform the retest. In response, the MRA responded that Viridis was prohibited from performing *any* analysis related to microbials. Viridis' customers have informed Viridis of the MRA's position and statements on its ability to perform microbial analysis.

167. The MRA told Viridis' customers one thing and Viridis another. They both were not correct, and the MRA took contrary positions.

168. The MRA refused to provide Viridis with adequate, written, or clear guidance on what it may do moving forward and actively sought to hinder their ability to address the recall with their customers.

169. The recall, by its very terms, allows cannabis products to be retested for microbial analysis. (**Exhibit W**). Because the MRA restricted and prevented Viridis from conducting microbial analysis, Viridis sought guidance from the MRA on what is needed to get re-authorization to test for microbials such that it can assist its customers.

170. In subsequent conversations with the MRA, it sent Viridis a "check list" of items that needed to be completed prior to it re-authorizing Viridis to complete microbial analysis. During a zoom call, the MRA revealed that the check list was even longer than originally anticipated, but represented that only the items listed in bold needed to be completed for Viridis to get up and running. In a follow up email, Viridis sought to verify what needed to be completed on the checklist (not the entire list but only bolded items). However, Julie Kluytman, the MRA's enforcement division director, changed the MRA's position yet again, moved the goal posts back, and indicated that *everything* on the checklist needed to be approved before Viridis could re-commence microbial testing. (**Exhibit U**).

171. Viridis managed to complete or substantially comply with every item listed on the checklist and sought the MRA's approval the following day. The MRA nevertheless rejected Viridis' efforts and demanded that it start its efforts over from scratch.

172. The MRA's above conduct had effectively suspended or restricted Viridis' licenses under Michigan law because it prohibits them from continuing to operate their business.

173. The MRA has consistently taken the position that its recall is warranted because, among other things, the public health and safety was at risk and, by extension, allowing Viridis to do *any* microbial testing puts the public's health and safety at risk. In these circumstances, the MRA was required to follow the procedures and processes set forth by statute and administrative rule to summarily suspend Viridis' licenses. MCL 24.292; MAC R. 420.705(1). It did not.

174. The MRA eventually capitulated after Viridis filed suit against it and several of its individual employees in the Court of Claims. (**Exhibit X**, Court of Claims Complaint). In an email, the MRA, through its counsel, indicated that Viridis was able to re-commence microbial testing. (**Exhibit Y**, Email). However, as late as November 27, 2021, Viridis and the MRA were still discussing the fact that the MRA's words and actions were not matching. The MRA would say one thing, and Viridis legitimately feared it would do another as further retribution for Viridis' lawful and proper actions.

175. To add further insult to injury, the MRA's "investigation" into Viridis has escalated to the point where the MRA is actively and voluntarily violating its own rules and technical guidance to facilitate retesting of Viridis' tested cannabis product in order to blame Viridis for a subsequent retest failure after the cannabis sample is no longer pristine for testing.

176. As of November 22, 2021, and subsequent to the unlawful recall, the MRA is now allowing growers to have samples that Viridis had originally tested as new samples transferred to other safety compliance facilities to be retested, after Viridis had already handled the sample and it is no longer pristine, and treating Viridis' test results as failed test.

177. The MRA is requiring these retests to have two consecutive passes and then allowing the growers to take the products to market.

178. These retests include samples that Viridis had tested that have been homogenized, cross-contaminated with unground foreign matter, had spatulas and had tweezers poked in the sample during the initial testing, and overall have been adulterated during the testing process.

179. The MRA is diverting from each marijuana safety compliance testing facility's approved SOPs and the MRA's own rules. *See, e.g.*, MAC R.420.306 ("A failed marijuana product must pass 2 separate tests *with new samples* consecutively to be eligible to proceed to sale or transfer.") (emphasis added); *Sampling and Testing Technical Guidance for Marijuana Products*, MRA, July 1, 2021, p 25, https://www.michigan.gov/documents/mra/Sampling_and_Testing_Technical_Guidance_for_Marijuana_Products_694124_7.pdf, ("A failed marijuana product must pass 2 separate tests with *new samples* consecutively to be eligible to proceed to sale or resale.").

180. These retests, which are using adulterated as opposed to new samples, have no scientific value or reliability. Even worse, the MRA has deliberately weaponized these unreliable results, repeatedly citing them in connection with conclusory scare tactics that seem designed solely to inflict as much damage as possible on Petitioners. For example, the MRA mentioned for the very first time during the COC PI hearing (broadcasted via YouTube) that 18 alleged adverse reports were received in connection with the recalled products. But the MRA has refused to share any additional information about those results, which is exactly the opposite of how adverse results reports are supposed to be handled. The MRA has also repeatedly refused to quantify how much product is now on the shelves that supposedly failed one of the faulty retests. Instead, the MRA insists on simply repeating the vague, conclusory scare tactic that some amount of product on the shelves supposedly failed a retest.

181. The MRA's conduct cannot be reviewed in a vacuum. It had stated publicly that it did not want a concentrated cannabis testing industry, and over the course of about one year, has specifically targeted Viridis for various "violations" that it cannot support with any substantial or reliable evidence.

182. Upon information and belief, the MRA's conduct was carried out by and amongst its employees to target Viridis for ulterior motives because of their market share in the cannabis testing industry.

183. Upon information and belief, the MRA's conduct was carried out in retaliation for Viridis using the proper and appropriate administrative channels for addressing its grievances with the MRA.

184. The MRA has significantly deviated from prior practice when dealing with violations of this nature, as explained below, opting to institute the largest cannabis product recall in the state's history. By doing so, it has discredited Viridis, their methods, and their principals.

185. A substantial number of Viridis' customers have already jumped ship to other marijuana safety compliance facilities to get their products on the market. Viridis is losing market share by the hour.

186. The MRA's wrongful conduct is the direct cause of all of this.

187. Since it issued the recall on November 17, 2021, the MRA has continued to target Viridis and undermine Viridis' business operations during its investigation at every juncture.

188. Immediately following the recall, the MRA, through Claire Patterson, contacted Maria McIntyre of bioMeireux, the same individual who it ignored when she challenged the recall, and requested that she analyze the data for Viridis' aspergillus GeneUp testing platform.

The reason Ms. Patterson contacted Ms. McIntyre was because no one at the MRA knew how to interpret the platform's data, and they needed Ms. McIntyre to interpret it for them.

189. Despite shifting its focus to aspergillus for a few weeks, the MRA has now, again, started issuing several administrative holds on METRC for "high" potency results and requiring that Viridis perform retests to verify potency results. The average for each week is greater than 40 retests and, to date, has exceeded 800 retests. The retests are, of course, inconsequential and pointless as Viridis achieves the same or substantially similar results, meaning there is nothing new for each retest the MRA requests.

190. The MRA has also, once again, started requesting on a weekly basis that Viridis provide significant data about its operations that Viridis knows for a fact that the MRA cannot open, interpret, or understand, including the information relating to the bioMerieux GeneUp platform.

191. The MRA has also take even effort to "jam up" Viridis in dealing with this administrative proceeding as well.

192. As indicated above, the MRA issued several administrative complaints relating to the Viridis Method for potency analysis. The MRA indicated in correspondence to Viridis that it intended to keep the materials confidential due to the salacious nature of the allegations and because it included Viridis' confidential and proprietary information. The MRA also indicated that it would not disclose them if requested via FOIA.

193. The MRA has again done an about face when Viridis inquired about the issue following the recall. The MRA has dodged Viridis' questions about whether FOIA requests have been received relating to the potency complaints, and refuses to even discuss whether it still intends to keep the complaints confidential.

194. Likewise, the MRA indicated to Viridis' counsel that it intended to file superseding complaints to rectify some or all of the issues with Viridis' confidential or proprietary information. However, to date, they have not filed those superseding complaints, leaving Viridis in the dark as to whether its confidential and proprietary information is going to be safeguarded against unlawful disclosure.

195. The MRA has even gone to great lengths to be sure that it strategically leaks investigate material to the press to put public pressure on Viridis' business operations. Just this week, MLive ran what can only be described as a "hit piece" on Viridis following the Court of Claims enjoining part of the recall. (**Exhibit Z**, Article). It describes cannabis products tested by Viridis as, among other things, "moldy" or "contaminated." MLive indicates through numerous sources that it purportedly received the information forming the basis of its article from the MRA following a FOIA request submitted to the MRA on December 14, 2021. The average turn around time for the MRA is several weeks, at best. But for this piece, the MRA somehow managed to have all documents prepared and released to MLive in *a single day*. The only conclusion that can be drawn from this is that the MRA made a targeted release to negatively affect Viridis' business operations.

196. The above-described requests and conduct are an excessive, unnecessary overreach by the MRA that will significantly disrupt Viridis' business operations and its operations as a marijuana safety compliance facility.

197. The above allegations, taken together and under the totality of the circumstances, evidence the MRA has continued to take step after step to interfere with Viridis' business. Viridis attempted to comply with the MRA's request, and in response, the MRA moved the goal posts to make compliance even more arduous and expensive.

198. The MRA's actions interfere with or impair the legal rights or privileges of Viridis.

199. The MRA's conduct is contrary to its own regulations and Michigan law.

COUNT I
INTERFERENCE WITH VIRIDIS' OPERATIONS THROUGH UNNECESSARILY
DISRUPTIVE INVESTIGATIVE PROCEDURES

200. Viridis reasserts and realleges the preceding paragraphs as if fully set forth herein.

201. Viridis Lansing and Viridis Bay City have a vested property interest in maintaining their licenses in good standing and a protected liberty interest in pursuing the vocation of their choosing

202. As explained in the numerous allegations above, the MRA has undertaken an excessive, unnecessary, and unreasonable campaign to investigate Viridis.

203. The MRA's campaign to unnecessarily and unreasonably investigate Viridis has now expanded into unrelated and unnecessary areas of Viridis' operations, as described above, and is contrary to Michigan law and its own regulations and technical guidance.

204. The MRA's investigatory actions have negatively impacted, interfered with, impaired, and disrupted Viridis' business operations and its operations as a marijuana safety compliance facility.

205. Among other things, Viridis has had to expend in excess of \$100,000 compiling the MRA's unreasonable and excessive video and information requests discussed above, and expend greater than 25 hours cumulatively in weekly labor hours attempting to comply with the MRA's requests. This has left a substantial backlog of tests that Viridis must complete to satisfy its obligations to its customers.

206. The MRA's campaign was unnecessary and unreasonable.

207. Viridis has suffered great economic harm as a result of the MRA's unwarranted activities.

WHEREFORE, Petitioners Viridis respectfully requests that the MRA cease its unreasonable and unnecessarily disruptive investigatory efforts, and that Viridis be allowed to continue its work without the MRA's unnecessary, unreasonable, and excessive interference with and disruption to its business operations and its operations as a marijuana safety compliance facility.

Respectfully submitted,

FOSTER, SWIFT, COLLINS & SMITH, P.C.
Counsel for Petitioners

Dated: January 7, 2021

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David R. Russell (P68568)
Brandon M. H. Schumacher (P82930)

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Co-Counsel for Petitioners

By: s/ Kevin M. Blair w/permission
Kevin M. Blair (P76927)

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Complaint, Ex. E

Outstanding Requests from the MRA to Viridis and Viridis North

Currently Outstanding Investigation Requests

1. Video footage of Viridis North. The last video request submitted to the MRA is not able to be viewed.
 - a. Please have Viridis North reach out to their RA and coordinate a time to pick up the requested footage. Please CC mra-scf@michigan.gov on this correspondence.
2. Potency prep sheets for all of the following samples:

LN-21-CS-24154,
LN-21-CS-24155
LN-21-CS-24156,
BC-21-CS-24158
BC-21-CS-24159
BC-21-CS-24160

3. Follow-up from email sent 10/7/2021
 - a. *"Can you please provide your calculation sheets for how you are calculating mold, pests, and powdery mildew. Do you document photographically the amount of total surface area of the sample and the amount which contains foreign matter?"*
4. Method of analysis added to Certificates of Analysis.

Currently Outstanding Method / Validation Requests

5. In order to approve updates made to the potency method (SOP LOM-7.1a Cannabinoid Analysis by HPLC-DAD), that is any updates that alter the method from the reference method, we require a complete validation to AOAC Appendix K. This also includes updates to the prep method that was approved by the MRA in January 2020.
 - a. Submit a validation report, with appropriate experimentation, statistical power, statistical design (e.g. RCBD or CRBD) and statistical analyses (e.g. ANOVA, Tukey HSD or Fisher LSD) to enable acceptance of the null hypothesis (Ho) and rejection of the alternative hypothesis (Ha). If this is the course the laboratory opts to pursue, we recommend that they identify someone who can assist them in the validation process. If there are any questions about the detailed requirements of what the MRA will accept, please contact mra-scf@michigan.gov and all assigned LSS's will provide guidance.
 - b. Alternatively, the laboratory may opt to run the reference method. If the laboratory opts to return to the reference method, they must also adhere to the appropriate SMPRs for the potency.
6. Microbiological Testing: In order to receive an approval for the requested microbial SOP matrix expansion, the laboratory must remove the section "Coliform Count using Aria" and the associated data Table 7 (pg. 12). Please reach out to the LSS if you have any additional questions please reach out to both assigned LSSs via mra-scf@michigan.gov

Outstanding Requests from the MRA to Viridis and Viridis North

7. Terpenoid Analysis: In order to receive approval for updates to LOM-7.7b-Terpenoid Analysis by Liquid Injection GC/MS for beverage matrix expansion, the laboratory must provide a reference that contains performance criteria. The method validation provided references a Sigma-Aldrich application note, yet it does not contain expected performance criteria. At minimum, this will be required to approve the method, however, providing this information does not ensure approval if more issues become apparent during the review of the next submission.
8. Chemical Residue: In order to receive approval for the requested Chemical Residue SOP matrix expansion, the laboratory must, at minimum, provide acceptable PT results for Diamonozid and Fibrinil as well as a corrective action report (CAPA) that addresses the aforementioned failures. Again, there may be additional items requested after subsequent review.

New Investigation Requests

9. Initial Demonstration of Capability (IDOC) for all technicians performing foreign matter analysis.
 - a. The document(s) used to train staff about identifying foreign matter as well as how to calculate foreign matter for the entire sample
10. All photos of samples which contain foreign matter detected in flower samples for the last 6 months.
11. All calculations performed for foreign matter for that past 30 days that determine whether a sample is pass or fail.
12. Please tell us how much sample is left in storage for the following Metrc samples (and if that amount is >0, please continue to hold these samples):

1A4050300005E89000000651
1A4050300005E89000000650
13. The SOP currently used by staff to complete Foreign Matter analysis
14. An instrument read-out of all tests performed on both the gene-up and aria platforms within the past 3 months.
15. Incubation logs for all Aspergillus tests performed in the month of September
16. A complete list of all currently employed methods, the date of the last update, and the date that the method was approved by the MRA as well as a copy of all SOPs currently in use.
17. A copy of all internal audits performed in 2020-2021.
18. A daily schedule of when analyses are typically performed, or if ongoing throughout the day, please let us know.

Outstanding Requests from the MRA to Viridis and Viridis North

- a. In addition, we will need several dates and times during the next two weeks for both Viridis locations when all technicians / analysts can be available for interview. We will be interviewing them independently to allow operations to continue in the rest of the lab.

Complaint, Ex. F

From: Gregoire Michaud [<mailto:gmichaud@viridisgrp.com>]
Sent: Friday, October 22, 2021 4:08 PM
To: Patterson, Claire (LARA)
Cc: Michael LaFramboise; Michele Glinn; Russell, David; Blair, Kevin M.; Kluytman, Julie (LARA)
Subject: RE: Tentative Audit Schedule

Here you go...have a nice weekend Claire.

Risa Hunt-Scully (P58239)
Assistant Attorney General
Michigan Department of Attorney General
Licensing & Regulation Division
3rd Floor, G. Mennen Williams Building
525 W. Ottawa Street
Lansing, Michigan 48933
(517) 335-7569
(517) 241-1997

Gregoire P. Michaud
CEO/Founder



"Ensuring Health & Safety Within Michigan's Cannabis Industry"

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Friday, October 22, 2021 4:05 PM
To: Gregoire Michaud <gmichaud@viridisgrp.com>
Cc: Michael LaFramboise <mLaframboise@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>; drussell@fosterswift.com; Blair, Kevin M. <KBlair@honigman.com>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>
Subject: RE: Tentative Audit Schedule

Hi Greg,

Would you please provide us the name of the AAG that you are working with on this case. We will need to touch base with them about shifting our investigation back, if necessary.

Thank you!

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

(517) 230-2097
PattersonC8@michigan.gov
www.michigan.gov/MRA



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From: Gregoire Michaud <gmichaud@viridisgrp.com>
Sent: Friday, October 22, 2021 3:51 PM
To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Cc: Michael LaFramboise <mlaframboise@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>; drussell@fosterswift.com; Blair, Kevin M. <KBlair@honiigman.com>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>
Subject: RE: Tentative Audit Schedule

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Claire,

My apologies for the late request here, but we've been attempting to coordinate a compliance conference with the AG's office which we have tentatively scheduled for November 2nd (see attached email). At the request of our legal counsel, we are hoping that you will be okay with rescheduling the audits until after the compliance conference has been held.

Kind regards,
Greg

Gregoire P. Michaud
CEO/Founder



"Ensuring Health & Safety Within Michigan's Cannabis Industry"

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Thursday, October 21, 2021 12:10 PM
To: Gregoire Michaud <gmichaud@viridisgrp.com>
Cc: Michael LaFramboise <milaframboise@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>
Subject: RE: Tentative Audit Schedule

It will be a combination of quality assurance audits, post-complaint audits, and investigatory audits. All will be strictly related to methods, processes, and SOPs. If you have any additional questions, please do not hesitate to ask.

Have a great day!

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

(517) 230-2097
PattersonC8@michigan.gov
www.michigan.gov/MRA



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From: Gregoire Michaud <gmichaud@viridisgrp.com>
Sent: Thursday, October 21, 2021 10:33 AM
To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Cc: Michael LaFramboise <milaframboise@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>
Subject: RE: Tentative Audit Schedule

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Yes, it clears up that portion of it, thank you Claire. Is this a quality assurance audit or a post-complaint, investigatory audit?

Gregoire P. Michaud
CEO/Founder



"Ensuring Health & Safety Within Michigan's Cannabis Industry"

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Thursday, October 21, 2021 9:53 AM
To: Gregoire Michaud <gmichaud@viridisgrp.com>; MRA-scf <MRA-scf@michigan.gov>; Michele Glinn <mglinn@viridisgrp.com>; Michael LaFramboise <milaframboise@viridisgrp.com>
Cc: Fields, Patrice (LARA) <FieldsP2@michigan.gov>; Rosenzweig, Noah (LARA) <RosenzweigN@michigan.gov>
Subject: RE: Tentative Audit Schedule

Good morning Greg,

I can jump in on this one, as I just want to make sure we are very clear about our intentions for the on-site event.

The plan is for the LSS staff to perform audits of the methods and procedures for routinely performed work as the work is being performed in real time. We do not plan on removing any staff from the laboratory or any of their duties to perform these audits. We will be asking questions related to the method and SOP, just as you would expect from any ISO audit.

Does that help answer your questions?

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

(517) 230-2097
PattersonC8@michigan.gov
www.michigan.gov/MRA



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From: Gregoire Michaud <gmichaud@viridisgrp.com>
Sent: Thursday, October 21, 2021 9:36 AM
To: MRA-scf <MRA-scf@michigan.gov>; Michele Glinn <mglinn@viridisgrp.com>; Michael LaFramboise <mlaframboise@viridisgrp.com>
Cc: Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Fields, Patrice (LARA) <FieldsP2@michigan.gov>; Rosenzweig, Noah (LARA) <RosenzweigN@michigan.gov>
Subject: RE: Tentative Audit Schedule

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Hi Allyson,

Will you be interviewing our team members individually when not observing them during the analytical processes?

Kind regards,
Greg

Gregoire P. Michaud
CEO/Founder



"Ensuring Health & Safety Within Michigan's Cannabis Industry"

From: MRA-scf <MRA-scf@michigan.gov>
Sent: Thursday, October 21, 2021 8:59 AM
To: Michele Glinn <mglinn@viridisgrp.com>; Michael LaFramboise <miaframboise@viridisgrp.com>;
Gregoire Michaud <gmichaud@viridisgrp.com>
Cc: Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Fields, Patrice (LARA) <FieldsP2@michigan.gov>; Rosenzweig, Noah (LARA) <RosenzweigN@michigan.gov>
Subject: Tentative Audit Schedule
Importance: High

Good morning,

Please see attached, if you have questions or concerns, please respond by COB Friday.

Allyson

Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency
MRA-scf@michigan.gov
www.michigan.gov/MRA

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Tentative Audit schedule for Viridis Lansing

Audit will occur October 26th

8:00-8:15am	Welcome introductions
8:15am-10:30	<p>Quality Systems Review</p> <p>Please have the following documents and records available for review and a staff member who is familiar and able to answer questions related to these items.</p> <ul style="list-style-type: none">• Quality Manual• All Testing SOPs
10:30-12:30	<p>Observation of Methods</p> <ul style="list-style-type: none">• Please have all remaining material for the following Metrc samples pulled and set aside.• Staff who prepare and run samples should be available for questions.• The MRA will be observing and asking questions, please have staff who are knowledgeable about the methods present.• Patrice will be observing all chemistry methods• Noah will be observing all microbial methods• Allyson will be observing foreign matter
12:30-1:30	lunch
1:30-3:00	Continuation of observation of methods
3:00-4:00	Additional Observation and questions
4:00-4:15	Exit Meeting

Please note that these times are flexible and may go longer or shorter than the timeframe noted.

Tentative Audit schedule for Viridis North

Audit will occur October 27th.

9:00-9:15am	Welcome introductions
9:15am-11:00	<p>Quality Systems Review Please have the following documents and records available for review and a staff member who is familiar and able to answer questions related to these items.</p> <ul style="list-style-type: none">• Quality Manual• All Testing SOPs
11:00-1:00	<p>Observation of Methods</p> <ul style="list-style-type: none">• Please have all remaining material for the following Metrc samples pulled and set aside.• Staff who prepare and run samples should be available for questions.• The MRA will be observing and asking questions, please have staff who are knowledgeable about the methods present.• Patrice will be observing all chemistry methods• Noah will be observing all microbial methods• Allyson will be observing foreign matter
1:00-2:00	lunch
2:00-3:30	Continuation of observation of methods
3:30-4:30	Additional Observation and questions
4:30-4:45	Exit Meeting

Please note that these times are flexible and may go longer or shorter than the timeframe noted.

October 28th will be a follow-up day if needed and we will notify at the exit meeting if we will be back and what time we are starting.

Complaint, Ex. G

From: MRA-scf

Sent: Monday, October 25, 2021 11:46 AM

To: Craig Runk ; Linda Palmatier ; Michele Glinn ; Gregoire Michaud ; Erik Nagler ; Steven Mayo ; skeeto1515@gmail.com

Cc: MRA-compliance

Subject: Request for Sample audit

Good Afternoon,

The Spott AU-SC-000105

The Marijuana Regulatory Agency (MRA) has selected 3 sample(s) for a safety compliance facility audit for aspergillus and potency.

Selected Packages:

Licensee #: Viridis Laboratory-Lansing AU-SC-000113

Package Name: Kush Mint Bud Metrc Tags #:

1A4050300009155000001014,1A4050300009155000001015, all remaining sample including extraction solution from the original testing.

Licensee #: Mitten Canna Co. (AU-G-C-000139)

3734 COMMERCE ST

Jackson, MI 49203

Package Name: MacFlurry Bud

Metrc Tag #: 1A4050300009155000000492

Contact Information for Assigned Laboratory:

Craig and Linda are included in the email contacts.

This sampling and testing event is being requested as part of MRA oversight authority in accordance with Marihuana Sampling and Testing R. 420.305(17) and (19):

(17) A laboratory shall comply with random quality assurance compliance checks upon the request of the agency. The agency or its authorized agents may collect a random sample of a marihuana product from a laboratory or designate another laboratory to collect a random sample of a marihuana product in a secure manner to test that sample for compliance pursuant to these rules.

(19) A laboratory shall comply with investigations to ensure the health and safety of the public. At the request of the agency, a laboratory may be requested to perform testing as part of an investigation.

Your marihuana business should not be charged for this testing event. It is necessary for the laboratory to take 0.5% of the sample from the source package, for the laboratory samples, the laboratory will provide all remaining sample.

Please contact MRA-scf@michigan.gov if you have questions or if the assigned laboratory fails to make contact within 2 business days by replying to this email or if you have questions.

Please reply to this email with the date and time for the sampling event so that the product holds can be lifted.

Best,

Allyson

Scientific & Legal Section

Enforcement Division

Marijuana Regulatory Agency

MRA-scf@michigan.gov

www.michigan.gov/MRA

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From: MRA-scf

Sent: Monday, October 25, 2021 11:52 AM

To: Mike Goldman ; Mac Hyman ; howard.l@ironlaboratories.com ; R Teitel ; Seth Tompkins ; Michele Glinn ; Gregoire Michaud

Cc: MRA-compliance

Subject: Request for Sample Audit

Good Afternoon,

Iron Laboratories AU-SC-000105

The Marijuana Regulatory Agency (MRA) has selected 3 sample(s) for a safety compliance facility audit for aspergillus and potency.

Selected Packages:

Licensee #: Viridis Laboratory-Lansing AU-SC-000113

Package Name: Blue Nina Flower Metrc Tags #:

1A40503000090EE000004021, 1A40503000090EE000004022, all remaining sample including extraction solution from the original testing.

Licensee #: The Calmic LLC (AU-G-C-000154)

655 Ballard RD

Jackson, MI 49201

Package Name: Blue Nina Flower

Metrc Tag #: 1A40503000090EE000003850

Contact Information for Assigned Laboratory:

The contacts for Iron are included on this email.

This sampling and testing event is being requested as part of MRA oversight authority in accordance with Marihuana Sampling and Testing R. 420.305(17) and (19):

(17) A laboratory shall comply with random quality assurance compliance checks upon the request of the agency. The agency or its authorized agents may collect a random sample of a marihuana product from a laboratory or designate another laboratory to collect a random sample of a marihuana product in a secure manner to test that sample for compliance pursuant to these rules.

(19) A laboratory shall comply with investigations to ensure the health and safety of the public. At the request of the agency, a laboratory may be requested to perform testing as part of an investigation.

Your marihuana business should not be charged for this testing event. It is necessary for the laboratory to take 0.5% of the sample from the source package, for the laboratory samples, the laboratory will provide all remaining sample.

Please contact MRA-scf@michigan.gov if you have questions or if the assigned laboratory fails to make contact within 2 business days by replying to this email or if you have questions.

Please reply to this email with the date and time for the sampling event so that the product holds can be lifted.

Best,

Allyson

Scientific & Legal Section

Enforcement Division

Marijuana Regulatory Agency

MRA-scf@michigan.gov

www.michigan.gov/MRA

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Save Michigan Lives.

From: MRA-scf

Sent: Monday, October 25, 2021 12:00 PM

To: Michele Glinn ; Gregoire Michaud ; Manik ; paulhansen@apothecareannarbor.com ; Manik

Cc: MRA-compliance

Subject: Request for Sample Audit

Good Afternoon,

Can-Lab AU-SC-000117

The Marijuana Regulatory Agency (MRA) has selected 3 sample(s) for a safety compliance facility audit for aspergillus and potency.

Selected Packages:

Licensee #: Viridis Laboratory-Lansing AU-SC-000113

Package Name: MAC #1 Flower #: 1A40503000090EE000003505, 1A40503000090EE000003506, all remaining sample including extraction solution from the original testing.

Licensee #: The Calmic LLC (AU-G-C-000154)

655 Ballard RD

Jackson, MI 49201

Package Name: MAC #1 Flower

Metric Tag #: 1A40503000090EE000004806

Contact Information for Assigned Laboratory:

Manik's email is in the contacts.

This sampling and testing event is being requested as part of MRA oversight authority in accordance with Marihuana Sampling and Testing R. 420.305(17) and (19):

(17) A laboratory shall comply with random quality assurance compliance checks upon the request of the agency. The agency or its authorized agents may collect a random sample of a marihuana product from a laboratory or designate another laboratory to collect a random sample of a marihuana product in a secure manner to test that sample for compliance pursuant to these rules.

(19) A laboratory shall comply with investigations to ensure the health and safety of the public. At the request of the agency, a laboratory may be requested to perform testing as part of an investigation.

Your marihuana business should not be charged for this testing event. It is necessary for the laboratory to take 0.5% of the sample from the source package, for the laboratory samples, the laboratory will provide all remaining sample.

Please contact MRA-scf@michigan.gov if you have questions or if the assigned laboratory fails to make contact within 2 business days by replying to this email or if you have questions.

Please reply to this email with the date and time for the sampling event so that the product holds can be lifted.

Best,

Allyson

Scientific & Legal Section

Enforcement Division

Marijuana Regulatory Agency

MRA-scf@michigan.gov

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From: MRA-scf

Sent: Monday, October 25, 2021 12:06 PM

To: howard.l ironlaboratories.com ; mike.g ironlaboratories.com ; mac.h ironlaboratories.com ; rob.t ironlaboratories.com ; Seth Tompkins ; Michele Glinn ; Gregoire Michaud

Cc: MRA-compliance

Subject: RE: Request for Sample Audit

Hi Howard,

You will make arrangements with Viridis-Lansing to obtain their remaining sample. It does not matter to the MRA if your lab picks up or if their lab drops off to you as long as a manifest is created for the transfer.

You will also make arrangements with the grower listed to sample from the harvest batch.

All samples will be run for aspergillus and potency.

Please let me know if you have additional questions, this is in response to an investigation so if you could make it a priority we would greatly appreciate it. Please send the COAs when complete as a response to this email.

I am available all day if a call is needed. I have included my signature line with my phone number.

Allyson

Dr. Allyson L. Chirio DHSc, MPH, BS(MT) (AMT)

Laboratory Scientist Specialist

Scientific & Legal Section, Enforcement Division

Marijuana Regulatory Agency

517-331-7512

ChirioA@michigan.gov

www.michigan.gov/MRA

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From: howard.l ironlaboratories.com

Sent: Monday, October 25, 2021 12:00 PM

To: MRA-scf ; mike.g ironlaboratories.com ; mac.h ironlaboratories.com ; rob.t ironlaboratories.com ; Seth Tompkins ; Michele Glinn ; Gregoire Michaud

Cc: MRA-compliance

Subject: Re: Request for Sample Audit

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Allyson,

Please explain the transport arrangements? I am confused by these instructions.

Best,
Howard

From: MRA-scf <MRA-scf@michigan.gov>
Sent: Monday, October 25, 2021 11:52 AM
To: mike.g ironlaboratories.com <mike.g@ironlaboratories.com>; mac.h ironlaboratories.com <mac.h@ironlaboratories.com>; howard.l ironlaboratories.com <howard.l@ironlaboratories.com>; rob.t ironlaboratories.com <rob.t@ironlaboratories.com>; Seth Tompkins <seth@sethtompkinslaw.com>; Michele Glinn <mglinn@viridisgrp.com>; Gregoire Michaud <gmichaud@viridisgrp.com>
Cc: MRA-compliance <MRA-compliance@michigan.gov>
Subject: Request for Sample Audit

Good Afternoon,

Iron Laboratories AU-SC-000105

The Marijuana Regulatory Agency (MRA) has selected 3 sample(s) for a safety compliance facility audit for aspergillus and potency.

Selected Packages:

Licensee #: Viridis Laboratory-Lansing AU-SC-000113

Package Name: Blue Nina Flower Metrc Tags #:

1A40503000090EE000004021,1A40503000090EE000004022, all remaining sample including extraction solution from the original testing.

Licensee #: The Calmic LLC (AU-G-C-000154)

655 Ballard RD

Jackson, MI 49201

Package Name: Blue Nina Flower

Metrc Tag #: 1A40503000090EE000003850

Contact Information for Assigned Laboratory:

The contacts for Iron are included on this email.

This sampling and testing event is being requested as part of MRA oversight authority in accordance with Marihuana Sampling and Testing R. 420.305(17) and (19):

(17) A laboratory shall comply with random quality assurance compliance checks upon the request of the agency. The agency or its authorized agents may collect a random sample of a marihuana product from a laboratory or designate another laboratory to collect a random sample of a marihuana product in a secure manner to test that sample for compliance pursuant to these rules.

(19) A laboratory shall comply with investigations to ensure the health and safety of the public. At the request of the agency, a laboratory may be requested to perform testing as part of an investigation.

Your marihuana business should not be charged for this testing event. It is necessary for the laboratory to take 0.5% of the sample from the source package, for the laboratory samples, the laboratory will provide all remaining sample.

Please contact MRA-scf@michigan.gov if you have questions or if the assigned laboratory fails to make contact within 2 business days by replying to this email or if you have questions.

Please reply to this email with the date and time for the sampling event so that the product holds can be lifted.

Best,

Allyson

Scientific & Legal Section

Enforcement Division

Marijuana Regulatory Agency

MRA-scf@michigan.gov

www.michigan.gov/MRA

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From: MRA-scf

Sent: Wednesday, October 27, 2021 12:32 PM

To: Craig Runk ; Linda Palmatier ; Michele Glinn ; Gregoire Michaud ; Steven Mayo ; skeeto1515@gmail.com ; Patrick Runk

Cc: MRA-compliance

Subject: RE: Request for Sample audit

Thanks Craig.

Compliance,

Please make sure to remove the hold prior to the sampling, and reinstate after sample creation.

Scientific & Legal Section

Enforcement Division

Marijuana Regulatory Agency

MRA-scf@michigan.gov

www.michigan.gov/MRA

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www.michigan.gov/COVIDvaccine.

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Save Michigan Lives.

From: Craig Runk

Sent: Wednesday, October 27, 2021 10:34 AM

To: MRA-scf ; Linda Palmatier ; Michele Glinn ; Gregoire Michaud ; Steven Mayo ; skeeto1515@gmail.com; Patrick Runk

Cc: MRA-compliance

Subject: RE: Request for Sample audit

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Hi,

The Spott will collect the specified samples tomorrow, 10/28/2021, between 9AM and 4 PM at the Lansing Viridis lab.

Thank You,

Craig Runk, MS

Laboratory Manager

The Spott

550 East Cork Street

Kalamazoo, MI 49001

Email: craigr@mispott.com

Phone: (269) 535-3668

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From: MRA-scf <MRA-scf@michigan.gov>

Sent: Monday, October 25, 2021 11:46 AM

To: Craig Runk <craig@mispott.com>; Linda Palmatier <lindap@mispott.com>; Michele Glinn <mglinn@viridisgrp.com>; Gregoire Michaud <gmichaud@viridisgrp.com>; Erik Nagler <erikn@mispott.com>; Steven Mayo <smayo23@icloud.com>; skeeto1515@gmail.com

Cc: MRA-compliance <MRA-compliance@michigan.gov>

Subject: Request for Sample audit

Importance: High

Good Afternoon,

The Spott AU-SC-000105

The Marijuana Regulatory Agency (MRA) has selected 3 sample(s) for a safety compliance facility audit for aspergillus and potency.

Selected Packages:

Licensee #: Viridis Laboratory-Lansing AU-SC-000113

Package Name: Kush Mint Bud Metrc Tags #:

1A4050300009155000001014, 1A4050300009155000001015, all remaining sample including extraction solution from the original testing.

Licensee #: Mitten Canna Co. (AU-G-C-000139)

3734 COMMERCE ST

Jackson, MI 49203

Package Name: MacFlurry Bud

Metrc Tag #: 1A4050300009155000000492

Contact Information for Assigned Laboratory:

Craig and Linda are included in the email contacts.

This sampling and testing event is being requested as part of MRA oversight authority in accordance with Marijuana Sampling and Testing R. 420.305(17) and (19):

(17) A laboratory shall comply with random quality assurance compliance checks upon the request of the agency. The agency or its authorized agents may collect a random sample of a marihuana product from a laboratory or designate another laboratory to collect a random sample of a marihuana product in a secure manner to test that sample for compliance pursuant to these rules.

(19) A laboratory shall comply with investigations to ensure the health and safety of the public. At the request of the agency, a laboratory may be requested to perform testing as part of an investigation.

Your marihuana business should not be charged for this testing event. It is necessary for the laboratory to take 0.5% of the sample from the source package, for the laboratory samples, the laboratory will provide all remaining sample.

Please contact MRA-scf@michigan.gov if you have questions or if the assigned laboratory fails to make contact within 2 business days by replying to this email or if you have questions.

Please reply to this email with the date and time for the sampling event so that the product holds can be lifted.

Best,

Allyson

Scientific & Legal Section

Enforcement Division

Marijuana Regulatory Agency

MRA-scf@michigan.gov

www.michigan.gov/MRA

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GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

ORLENE HAWKS
DIRECTOR

November 15, 2021

Viridis Laboratories, LLC-SC-000009/AU-SC-000113
2827 E. Saginaw Lansing, MI 48912
Date of Audit: 10/26/2021
Compliance Monitoring Tier 4

Onsite Audit Findings

Auditors: Dr. Noah Rosenzweig, Dr. Patrice Fields, Dr. Allyson Chirio & Claire Patterson (oversight)

As requested during the onsite audit by Michele Glinn, at the end of this document, you will find a summary of qualifications for each auditor and the methods they were responsible for reviewing.

Dear Viridis Laboratories, LLC,

An onsite compliance audit was conducted at your facility on 10/26/2021, several non-conformances were identified. The nonconformances are listed below.

Nonconformance 1

R. 420.305 (1) A laboratory shall do all of the following: (b) Maintain internal standard operating procedures for the required safety tests in subrule (3) of this rule and for sampling of marihuana and marihuana products that conform to ISO/IEC 17025:2017 standards and have been approved by the agency.

R. 420.305 (1) (c) Maintain a quality control and quality assurance program that conforms to ISO/IEC 17025:2017 standards and meets the requirements established by the agency.

R. 420.305(2) A laboratory shall use analytical testing methodologies for the required safety tests in subrule (3) of this rule that are validated by an independent third party and may be monitored on an ongoing basis by the agency or a third party. In the absence of reference to compendia or published methods, Appendix K of Official Methods of Analysis authored by the Association of Official Analytical Chemists must be published in full. The agency shall approve the validated methodology used by the laboratory and confirm that it produces scientifically accurate results for each safety test it conducts.

Laboratory technicians are not following approved foreign matter SOP - LOM - 7. 11 Foreign Matter Analysis and Photographic Imaging. Laboratory is not failing samples which exceed the 2% action limit.

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LARA is an equal opportunity employer/program.

Deviations observed and documented include:

1. Dr. Chirio observed samples viewed at only minimal magnification. LSS Chirio did not observe the technician use the dino scope for higher power viewing for viewing pests, powdery mildew and other organic matter that is not visible on low magnification.
2. Dr. Chirio asked the technician (Kylie) performing foreign matter if they ever view samples on the dino scope which is a higher magnification and she stated "no, we only use it for pictures".
3. Dr. Chirio observed visible mold more than 2% in a sample which Laboratory Director Michele Glinn told the laboratory technician Kylie to pass.
4. It should be noted that Michele Glinn, laboratory director who per the approved SOP LOM - 7. 11 Foreign Matter Analysis and Photographic Imaging is one of the supervisors who can verify foreign matter failures. Michele Glinn was unable to visualize the sample herself, she asked the technician multiple times to point out where the contamination was located.
5. She stated that the foreign material was mite poop, not enough to fail and not visible mold.
6. When Dr. Chirio asked for clarification on how 2% is calculated for a mold failure, she was told by Michele Glinn the sample containing visible mold would have to cover more than 2 squares on the grid used. The sample was greater than 2 squares and there was additional material that should have been included in the calculation which was not. Please refer to the picture of the sample taken noted as figure 1. Michele Glinn also stated that if mold was present, it would be caught on the total yeast and mold analysis.
7. Claire Patterson and Dr. Rosenzweig both with extensive backgrounds in plant biology and pathology confirmed the presence of the mold on the sample.



Figure 1. Sample 26182 Metrc last 4 digits 4884.

Nonconformance 2

R. 420.305 (1) A laboratory shall do all of the following: (b) Maintain internal standard operating procedures for the required safety tests in subrule (3) of this rule and for sampling of marihuana and marihuana products that conform to ISO/IEC 17025:2017 standards and have been approved by the agency.

R. 420.305 (1) (c) Maintain a quality control and quality assurance program that conforms to ISO/IEC 17025:2017 standards and meets the requirements established by the agency.

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Deviations observed and documented include:

Viridis laboratories is not adhering to the method specifications. Sample incubation times are not tracked, the laboratory could not provide documentation that the methods were performed as validated.

1. The approved SOP LOM 22 Detection of Yeast and Mold by Tempo requires yeast and mold to incubate for 72-76 hours at $25 \pm 1^{\circ}\text{C}$ (24-26°C).
2. Incubator I2 Identified by Ross White is used for total yeast and mold samples, at the time of inspection the temperature was 25°C, the log sheet (see figure 2 below) provided shows the temperature outside of the manufacture validated specifications exceeding 26°C from 08/10/2021-10/6/2021.
3. The approved LOM 21 Detection of Salmonella and STEC by GENE-UP requires samples to be incubated at 41.5°C for 24 – 28 hours. There are several instances on the incubator log where the incubation temperature exceeds 41.5°C. Refer to figure 2. Below.
4. Manager Claire Patterson asked Ross White if incubation time in and time out are recorded and logged, Ross stated that it is not recorded. There is no way to confirm that samples have been incubated the appropriate length of time as samples are not tracked on worklists where the technician could note the last sample placed in incubator and when the run was taken out for testing.
5. There are no documented non-conformances or evidence that Viridis is aware of the temperature deviations or has performed any corrective actions or repeat analysis for nonconforming samples, samples which were found to not contain TYM, Salmonella and STEC are not valid (passing samples) due to the deviations from the specific validated temperatures .
6. According to SOP-QM - 6.3 Facilities and Environmental Conditions "Viridis Laboratories monitors, controls, and records environmental conditions as required by relevant specifications, methods, or procedures or where they may influence the quality of the results." The methods call for strict adherence to temperature and time specifications and continuous

monitoring, which is not being done. Incubator temperatures are only checked once per day in the morning.

7. According to SOP QM-8.9 Management Reviews states "Are environmental conditions or facility problems adversely affecting the test results?" Per Dr. Michele Glinn she or her designee review temperature charts not less than monthly, the logs are not signed and the deviations from the approved methods and nonconforming testing results have not been evaluated as far as the MRA is aware. During the audit the MRA did ask to view the Current CAPAs and there were not any internally generated complaints.

8. According to SOP QM - 7.10 Non-Conforming Work "Viridis Laboratories has a procedure for handling laboratory activities that does not conform to its procedures or to the agreed requirements of the client. (QM - 8.7 Corrective Actions) Calibration/test data not conforming to established acceptance criteria are controlled and are not released to the client. Any nonconforming calibration/test items that do not match the requirements are identified, managed and prevented from unintended delivery to the client." Viridis is not adhering to their SOP, results were all released without investigation. As far as the MRA is aware Viridis has not made any attempt to notify clients, the MRA or investigate how many samples are non-conforming.

Incubator Maintenance / Temperature Log										Incubator: 11, 12, 13, MicroFridge (MF)	
8/10/21	37.0	8/10/21	41.5	8/10/21	28.1	8/10/21	4.6				
8/11/21	37.0	8/11/21	41.5	8/11/21	27.1	8/11/21	4.0				
8/12/21	36.9	8/12/21	41.5	8/12/21	26.9	8/12/21	4.0				
8/13/21	37.0	8/13/21	28.6	8/13/21	41.5	8/13/21	5.5	7/14/21	32 + 33 success		
8/14/21	37.1	8/14/21	28.5	8/14/21	41.5	8/14/21	4.1				
8/15/21	37.0	8/15/21	28.4	8/15/21	41.6	8/15/21	5.0				
8/16/21	37.0	8/16/21	28.5	8/16/21	41.5	8/16/21	4.1	8/20/21	34 - 35.0		
8/17/21	37.0	8/17/21	28.5	8/17/21	41.5	8/17/21	5.0	8/27/21	34 - 35.0		
8/18/21	37.0	8/18/21	27.9	8/18/21	41.5	8/18/21	5.5	8/30/21	34 - 35.0		
8/19/21	37.0	8/19/21	28.9	8/19/21	41.6	8/19/21	4.7	9-2-21	34 - 35.0		
8/20/21	37.0	8/20/21	28.9	8/20/21	41.5	8/20/21	5.1	9-5-21	34 - 35.0		
8/21/21	37.0	8/21/21	28.5	8/21/21	41.5	8/21/21	4.7	9-8-21	34 - 35.0		
9/10/21	37.0	9/10/21	28.3	9/10/21	41.5	9/10/21	4.2	9/10/21	34 - 35.0		
9/13/21	37.0	9/13/21	28.0	9/13/21	41.5	9/13/21	3.8	9/13/21	34 - 35.0		
9/14/21	37.0	9/14/21	27.5	9/14/21	41.4	9/14/21	3.8	9/14/21	34 - 35.0		
9/15/21	37.0	9/15/21	28.0	9/15/21	41.7	9/15/21	4.0	9/15/21	34 - 35.0		
9/16/21	37.0	9/16/21	29.1	9/16/21	41.0	9/16/21	4.5	9/16/21	34 - 35.0		
9/18/21	37.0	9/18/21	29.0	9/18/21	41.0	9/18/21	3.9	9/18/21	34 - 35.0		
9/19/21	37.0	9/19/21	29.6	9/19/21	41.5	9/19/21	4.9	9/19/21	34 - 35.0		
9/20/21	37.0	9/20/21	28.9	9/20/21	41.5	9/20/21	4.0	9/21/21	34 - 35.0		
9/21/21	37.0	9/21/21	28.7	9/21/21	41.5	9/21/21	4.4	9/22/21	34 - 35.0		
9/22/21	37.0	9/22/21	29.7	9/22/21	41.5	9/22/21	4.9	9/23/21	34 - 35.0		
9/23/21	37.0	9/23/21	29.0	9/23/21	41.2	9/23/21	4.7	9/24/21	34 - 35.0		
9/24/21	37.1	9/24/21	29.3	9/24/21	41.7	9/24/21	4.6	9/25/21	34 - 35.0		
9/25/21	37.0	9/25/21	29.4	9/25/21	41.5	9/25/21	4.5	9/26/21	34 - 35.0		
9/27/21	37.0	9/27/21	27.9	9/27/21	41.5	9/27/21	4.0	9/28/21	34 - 35.0		
9/28/21	36.9	9/28/21	29.2	9/28/21	41.5	9/28/21	4.6	9/29/21	34 - 35.0		
9/29/21	37.0	9/29/21	29.0	9/29/21	41.5	9/29/21	3.9	9/30/21	34 - 35.0		
10/1/21	37.0	10/1/21	29.6	10/1/21	41.6	10/1/21	4.6	10/1/21	34 - 35.0		
10/5/21	37.0	10/5/21	29.5	10/5/21	41.4	10/5/21	5.1	10/5/21	34 - 35.0		
10/6/21	37.0	10/6/21	28.7	10/6/21	41.4	10/6/21	5.3	10/6/21	34 - 35.0		

Figure 2. Viridis Lansing Incubator temperature log

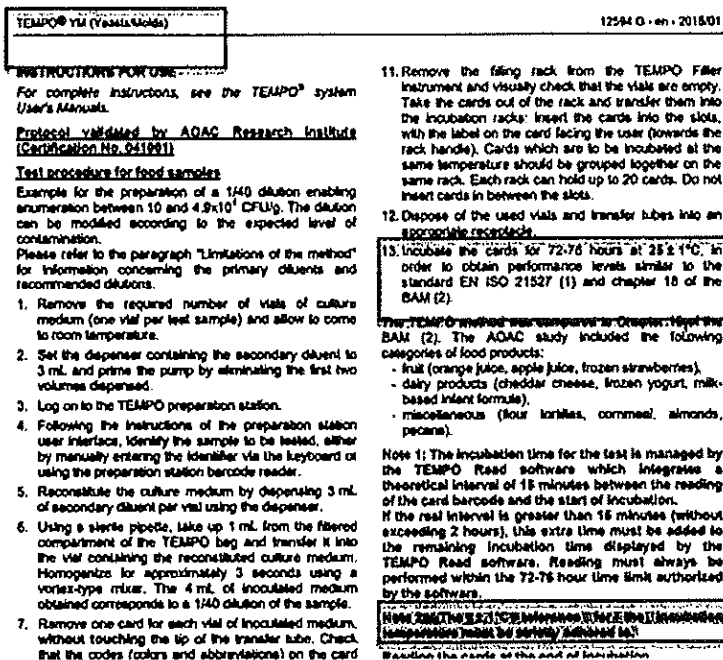


Figure 3. Package insert for the Tempo platform

DISCUSSION OF MODIFICATION APPROVED NOVEMBER 16, 2020 (14)

The GENE-UP *Salmonella* method successfully detected *Salmonella* from whole cannabis flower (10 g & 1 g) and whole hemp flower (10 g & 1 g) after 18 h of primary enrichment. Using POD analysis, no statistically significant differences were observed between the number of positive portions detected by the candidate method presumptive and confirmed results. No discrepant results were obtained with the validation study.

The GENE-UP *Salmonella* method is quick and simple to perform, providing results in less than 1.5 h post incubation of the selective enrichment for 30 sample replicates. With ready-to-use lyophilized PCR reagents, it allows the user to conduct PCR without an additional step of adding the master mix, reducing the amount of hands-on time during PCR which eliminates the chance of contamination. The GENE-UP software is user friendly with the ability to track lot information and sample identification quickly and with ease.

Table 2. GENE-UP *Salmonella* Results - Presumptive vs. Confirmed (14)

Matrix/Test Portion	Inoculum	MPN/ Test Portion	N ^a	x ^b	Presumptive POD _{pr} ^c	95% CI	x	Confirmed POD _{cc} ^c	95% CI	dPOD _{cc} ^d	95% CI ^e
Whole cannabis flower (10 g)	<i>Salmonella</i>	N/A ^f	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
	<i>Typhimurium</i>	0.74 (0.38, 1.28)	20	9	0.45	0.26, 0.66	9	0.45	0.26, 0.66	0.00	-0.13, 0.13
	ATCC 14028	4.20 (1.71, 10.3)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Whole cannabis flower (1 g)	<i>Salmonella</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
	<i>Typhimurium</i>	0.91 (0.50, 1.54)	20	10	0.50	0.30, 0.70	10	0.50	0.30, 0.70	0.00	-0.13, 0.13
	ATCC 14028	4.20 (1.71, 10.3)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Whole hemp flower (10 g)	<i>Salmonella</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
	<i>Enteritidis</i>	1.33 (0.86, 2.19)	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.13, 0.13
	ATCC 13076	6.16 (1.91, 19.9)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Whole hemp flower (1 g)	<i>Salmonella</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
	<i>Enteritidis</i>	0.71 (0.41, 1.19)	20	7	0.35	0.18, 0.57	7	0.35	0.18, 0.57	0.00	-0.13, 0.13
	ATCC 13076	4.13 (1.46, 11.7)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47

^aMPN = Most Probable Number is calculated using the LCF MPN calculator provided by AOAC RI, with 95% confidence interval.

^bN = Number of test portions.

^cx = Number of positive test portions.

^dPOD_{pr} = Candidate method presumptive positive outcomes divided by the total number of trials.

^ePOD_{cc} = Candidate method confirmed positive outcomes divided by the total number of trials.

^fdPOD_{cc} = Difference between the candidate method presumptive and confirmed POD values.

^g95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

^hATCC = American Type Culture Collection, Manassas, VA.

ⁱN/A = Not applicable

Figure 4. Performance tested method specifications for *Salmonella* these are the same for STEC

MICROVAL Approved Protocols (2018LR84)	
Matrix	Protocol
Raw milk products (up to 25 g or 25 mL)	<ul style="list-style-type: none"> • X g (X mL) of sample. • 9X mL of buffered peptone water (BPW). • Mix using a paddle blender. • Incubate at $+37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 18-26 hours.

Note: For environmental samples, the collection device should first be dampened with a sterile diluent (for example, buffered peptone water) containing, if necessary, a suitable neutralizing agent (for example, Lecithin-Polysorbate-L-Histidine-Sodium thiosulfate mixture or Dey Engley).

Protocols Outside of Certification	
Matrix	Protocol
Vegetables (up to 25 g)	<ul style="list-style-type: none"> • X g of sample. • 9X mL of buffered peptone water (BPW). • Mix using a paddle blender. • Incubate at $+41.5^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 18-26 hours.

Note: Incubation conditions may have repercussions on short detection procedures. The temperature conditions indicated must be scrupulously respected. In particular, ensure that the enrichment broth preheating conditions allow for the specified temperature to be reached. The sample preparation time, which is the time between the end of the enrichment broth preheating phase and the start of the sample incubation phase, must not exceed 45 minutes. It is recommended to use a ventilated incubator for the incubation phase.

Figure 5. Package Insert for STEC

Nonconformance 3

420.210 (2) Except for a designated consumption establishment or temporary marihuana event licensed under the Michigan regulation and taxation of marihuana act, a marihuana business must not have any marihuana product without a batch number or identification tag or label pursuant to these rules. A licensee shall immediately tag, identify, or record as part of a batch in the statewide monitoring system any marihuana product as provided in these rules.

Deviations observed and documented include:

Viridis laboratories has marihuana product onsite without Metrc tags.

1. Dr. Chirio observed foreign matter and microbial samples without Metrc tag numbers.



Figure 6. Marihuana Product without Metric tags.

Additional Observations

Deviations observed and documented include:

Viridis laboratories is not adhering to the SOP- LOM - 7. 4 Chemical Residue _ Pesticide Analysis by LC-MS_MS and the specific storage requirements for the chemical residue standards used.

1. During the visit to Viridis North, Dr. Fields observed laboratory scientist Ethan preparing to add samples to an existing analysis batch, an analysis batch is a group of samples, sample extracts, or sample digestates (including QC aliquots), that are analyzed together on the same instrument. The analysis batch was started the previous afternoon (10/26/21). Calibration of the instrument only occurs at the start of the testing batch. The calibration curve defines the relationship between the detector response and the concentration of analyte in the sample matrix. Dr. Fields confirmed the calibration curve and quality control checks used to quantitate the samples were prepared 10/26/2021 and were on the instrument overnight at room temperature. Prepared standards if not stored properly can cause inaccurate results. The Restek standards used come frozen and are temperature labile, keeping them on an instrument at room temperature will cause degradation. Degraded standards will cause the responses to be higher for samples since the concentrations of the analytes in the standards will be decreased. Meaning that the laboratory could inaccurately report chemical residues where there are none present or report chemical residues at higher concentrations than what is actually in the sample.

NOTE: This finding is being included on the Lansing findings as the operations were stated to be duplicated. At the time of the Lansing audit, chemical residue samples were not running, so the MRA was not able to review this method. If this same procedure is not occurring at the Lansing location, please respond to this nonconformance with documentation how the procedure differs for the Lansing location.

[illegible]

Case, as Subject	Case#	May 2001 Life Span Day Range	May 2001 Life Span Day Range	Shipping Conditions	Storage Temp.	Wt.	MLB
Organic Pyrethroids: Residual 1							
600 pyval, Acetamix 1.0 (1 sample)	Yes	6 months	12 months	Acetamix	-10 °C or colder	60	1.544
600 pyval, Acetamix 1.0 (1 sample)	Yes	6 months	12 months	Acetamix	-10 °C or colder	60	1.543
Organic Pyrethroids: Residual 2							
600 pyval, Acetamix 1.0 (1 sample)	Yes	6 months	12 months	Acetamix	-10 °C or colder	60	1.543
600 pyval, Acetamix 1.0 (1 sample)	Yes	6 months	12 months	Acetamix	-10 °C or colder	60	1.543
Organic Pyrethroids: Residual 3							
600 pyval, Acetamix 1.0 (1 sample)	Yes	6 months	12 months	Acetamix	-10 °C or colder	60	1.543
600 pyval, Acetamix 1.0 (1 sample)	Yes	6 months	12 months	Acetamix	-10 °C or colder	60	1.543
Organic Pyrethroids: Residual 4							
600 pyval, Acetamix 1.0 (1 sample)	Yes	6 months	12 months	Acetamix	-10 °C or colder	60	1.543
600 pyval, Acetamix 1.0 (1 sample)	Yes	6 months	12 months	Acetamix	-10 °C or colder	60	1.543

Figure 7. Restek storage conditions

Corrective actions required to be completed ASAP listed below.

1. The laboratory shall immediately log this as a complaint and follow their complaint procedure QM-7.9 Complaints, Non-conforming work QM-7.10 Non-Conforming Work and Corrective action QM-8.7 Corrective Actions.
2. Due to the severity and public health implications for the many failures of the existing quality management system, the MRA is requesting a full regulatory audit conducted by the accrediting body or another 3rd party accreditor, the results of this audit shall be shared directly with the MRA from the auditor at the same time they are sent to the facility. The MRA would like to be present for this audit, please notify us of the date and time.
3. The laboratory shall immediately institute a method for tracking samples in and out of incubators. Management shall review these with the temperature logs before results are reported to ensure accurate results in compliance with their QM-7.7 Ensuring the validity of results SOP.
4. The laboratory shall immediately institute continuous temperature monitoring for all incubators and update their current environmental monitoring SOP-QM - 6.3 Facilities and Environmental Conditions to include monitoring incubators.
5. The laboratory shall immediately revise current temperature logs to include the method specific ranges and corrective actions. At no such time should microbial results be reported if the temperature is outside of the acceptable validated ranges or if the samples have not been incubated within the acceptable timeframes found in the specific method package inserts.
6. The laboratory shall immediately assign a manager to review temperature logs, logs shall be signed and dated when reviewed, this should be added to the management review SOP QM-8.9 Management Reviews.
7. The laboratory shall compile a list of ALL nonconforming samples and immediately provide the list to the agency. The laboratory should do a look back on all previously reported microbial testing and qualify results where they cannot demonstrate appropriate incubation time.
8. The laboratory shall provide all PCR run data directly from the instrument for all microbial methods from 8/10/2021 to current.
9. The laboratory shall immediately conduct a thorough root cause analysis for the nonconformances identified in this report and provide all documents to the MRA.
10. The laboratory shall immediately correct the foreign matter results of sample 26182 Metrc last 4 digits 4884 to failing. Once this is completed, please send email notification to MRA-SCF@michigan.gov and the hold will be removed.
11. The laboratory shall immediately do a look back on samples in current inventory which have been passed for foreign matter and shall repeat the inspection following the approved SOP and additional training provided to staff from Claire Patterson during the Viridis North audit 10/27/2021, Michael Laframboise was present and should be lead on retraining all staff at both locations.
12. If non-conforming foreign matter samples are identified, the laboratory will update all test results in Metrc and provide a list of all samples.
13. Immediately, Viridis laboratories needs to label marihuana product with the full Metrc tag number assigned in the statewide monitoring system. The only marihuana product onsite that

does not require a Metrc tag number would be any compliantly obtained patient/caregiver material. This finding was observed during the December 2020 semi-annual inspection for Viridis North where Michele Glinn was present and has not been corrected, this needs to be corrected immediately.

14. The MRA is requesting a copy of all complaints and CAPAs for the last year to ensure there are no additional areas of concern.

Complaint, Ex. I



GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

ORLENE HAWKS
DIRECTOR

November 15, 2021

Viridis Laboratories North, LLC-SC-000014/AU-SC-000103
1424 Straits Dr, Bay City, 48706-8705, MI
Date of Audit: 10/27/2021
Compliance Monitoring Tier 4

Onsite Audit Findings

Auditors: Dr. Noah Rosenzweig, Dr. Patrice Fields, Dr. Allyson Chirio & Claire Patterson

Dear Viridis Laboratories North, LLC,

An onsite compliance audit was conducted at your facility on 10/27/2021, several non-conformances were identified. The nonconformances are listed below.

Nonconformance 1

R. 420.305 (1) A laboratory shall do all of the following: (b) Maintain internal standard operating procedures for the required safety tests in subrule (3) of this rule and for sampling of marihuana and marihuana products that conform to ISO/IEC 17025:2017 standards and have been approved by the agency.

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Laboratory technicians are not following approved foreign matter SOP - LOM - 7. 11 Foreign Matter Analysis and Photographic Imaging. Laboratory is not failing samples which exceed the 2% action limit.

Deviations observed and documented include:

MARIJUANA REGULATORY AGENCY
2407 NORTH GRAND RIVER • LANSING, MICHIGAN 48909
www.michigan.gov/lara
LARA is an equal opportunity employer/program.

1. Dr. Chirio, Dr. Rosenzweig, Dr. Fields and Claire Patterson all observed samples viewed at only minimal magnification. LSS Chirio did not observe the technician use the dinoscope for higher power viewing for pests, powdery mildew and other organic matter that is not visible on low magnification.
2. Dr. Chirio asked Laboratory Manager Michael LaFramboise several questions related to foreign matter, and he was unable to answer specifics but is the supervisor who would confirm the presence of foreign matter. Dr Chirio specifically asked Manager Michael LaFramboise at which power are the technicians viewing samples, she also asked both technicians performing the inspections, none of the staff were able to answer the question. After the finding conference the objective power was determined to be 40x, this is minimal magnification and most foreign matter would not be visualized. The SOP states that staff will review on low power determined to be 40x and then additionally on higher power of at least 100x.
3. Dr. Chirio asked the technicians if they view samples using the higher power magnification and the technicians said they only use the higher power for taking photographs of the product.
4. Claire Patterson reviewed a sample which contained powdery mildew while onsite, she spent time with the staff showing them powdery mildew and assisting them with being able to identify foreign matter, Manager Michael LaFramboise was present during the short training.



Figure 1. Technician setup for foreign matter under low power

Nonconformance 2

R. 420.305 (1) A laboratory shall do all of the following: (b) Maintain internal standard operating procedures for the required safety tests in subrule (3) of this rule and for sampling of

marihuana and marihuana products that conform to ISO/IEC 17025:2017 standards and have been approved by the agency.

R. 420.305 (1) (c) Maintain a quality control and quality assurance program that conforms to ISO/IEC 17025:2017 standards and meets the requirements established by the agency.

R. 420.305(2) A laboratory shall use analytical testing methodologies for the required safety tests in subrule (3) of this rule that are validated by an independent third party and may be monitored on an ongoing basis by the agency or a third party. In the absence of reference to compendia or published methods, Appendix K of Official Methods of Analysis authored by the Association of Official Analytical Chemists must be published in full. The agency shall approve the validated methodology used by the laboratory and confirm that it produces scientifically accurate results for each safety test it conducts.

Deviations observed and documented include:

Viridis laboratories North is not adhering to the method specifications. Sample incubation times are not tracked, the laboratory could not provide documentation that the methods were performed as validated.

1. Dr. Rosenzweig asked Bradley Phelps, while observing him prepping samples for incubation if he had a workorder/worksheets/plate map to ensure chain of custody of samples through the testing process for sample tracking but was not provided one. When asked again how samples were tracked Brandon Lucius responded, "I just have a system".
2. Viridis laboratories North is not tracking when samples are placed in incubators or removed from incubators. There is no way for the MRA to know if samples have been incubated the appropriate length of time. Viridis Laboratories North could not provide documentation that samples were incubated the minimum length and did not exceed the maximum length.
3. According to SOP-QM - 6.3 Facilities and Environmental Conditions "Viridis Laboratories monitors, controls, and records environmental conditions as required by relevant specifications, methods, or procedures or where they may influence the quality of the results."
4. During the ISO accreditation audit completed 09/13/2021, Viridis North Laboratories received a deficiency stating the following "The laboratory could not produce records of verification of temperatures in the four different incubators required for its microbial procedures. One incubator did not have a temperature-measuring device in place." Please refer to Figure 1.
5. All samples reported when temperatures were not being tracked 8/10/2021-9/14/2021 are non-conforming samples and corrective action should have been taken in compliance with laboratory procedures. As the MRA has not received a list of samples or notification of the nonconformances, it is assumed that the corrective action procedures were not adhered to for these samples. **If corrective action procedures were adhered to, please provide those to the MRA as soon as possible.**

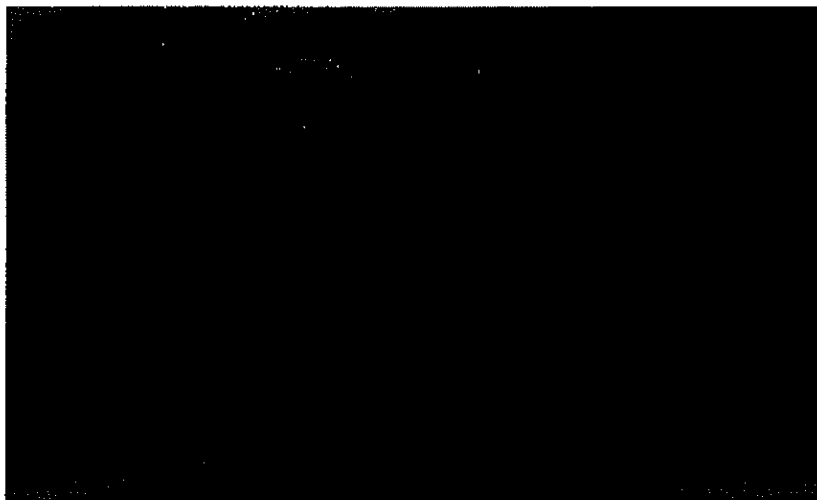


Figure 2. ISO accreditation audit findings

Nonconformance 3

420.210 (2) Except for a designated consumption establishment or temporary marihuana event licensed under the Michigan regulation and taxation of marihuana act, a marihuano business must not have any marihuana product without a batch number or identification tag or label pursuant to these rules. A licensee shall immediately tag, identify, or record as part of a batch in the statewide monitoring system any marihuana product as provided in these rules.

R. 420.305 (1) (c) Maintain a quality control and quality assurance program that conforms to ISO/IEC 17025:2017 standards and meets the requirements established by the agency.

Deviations observed and documented include:

Viridis laboratories North has marihuana product onsite without Metrc tags.

1. Dr. Chirio observed foreign matter and microbial samples without Metrc tag numbers.



Figure 3. Marihuana Product without Metrc tags.

Nonconformance 4

R. 420.305 (1) (c) Maintain a quality control and quality assurance program that conforms to ISO/IEC 17025:2017 standards and meets the requirements established by the agency.

Deviations observed and documented include:

Viridis laboratories North has a biochemical hood in use for microbial sample preparation with an expired calibration. This is not in compliance with SOP-6.3 Facilities and Environmental Conditions.

1. Dr. Chirio observed the expired calibration listed below as figure 3.

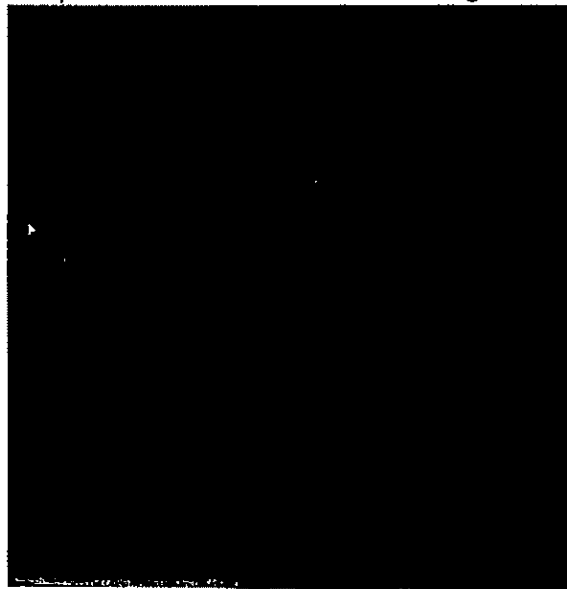


Figure 4. Compliance sticker for biochemical hood in use

Additional Observations

Deviations observed and documented include:

Viridis laboratories North is not adhering to the SOP- LOM - 7. 4 Chemical Residue _ Pesticide Analysis by LC-MS_MS and the specific storage requirements for the chemical residue standards used.

1. During the visit to Viridis North, Dr. Fields observed laboratory scientist Ethan preparing to add samples to an existing analysis batch, an analysis batch is a group of samples, sample extracts, or sample digestates (including QC aliquots), that are analyzed together on the same instrument. The analysis batch was started the previous afternoon (10/26/21). Calibration of the instrument only occurs at the start of the testing batch. The calibration curve defines the relationship between the detector response and the concentration of analyte in the sample

matrix. Dr. Fields confirmed the calibration curve and quality control checks used to quantitate the samples were prepared 10/26/2021 and were on the instrument overnight at room temperature. Prepared standards if not stored properly can cause inaccurate results. The Restek standards used come frozen and are temperature labile, keeping them on an instrument at room temperature will cause degradation. Degraded standards will cause the responses to be higher for samples since the concentrations of the analytes in the standards will be decreased. Meaning that the laboratory could inaccurately report chemical residues where there are none present or report chemical residues at higher concentrations than what is actually in the sample.

Oregon Cannabis Pesticide standards meet the specific cannabis pesticide residue analysis needs of Oregon and states with similar pesticide residue regulatory programs. Dissolved in acetonitrile and for stability, the 39 compounds are separated into 6 > 1 mL solutions with individual analyte concentrations of 600 µg/mL resulting in a convenient 100 µg/mL solution when blended immediately before use. Designed with quality and convenience in mind, this set of standards eliminates the need for in-house standard preparation. Restek Oregon Pesticide Standards are certified reference materials (CRM) manufactured and QC tested in ISO-accredited lab.

<p>Each sample vial separately</p> <p>Cal # 12766: Oregon Pesticide Standard P1 (12 compounds)</p> <p>Abamectin (12766-01-2) Acephate (12766-02-3) Acetamiprid (12766-03-4) Bifenthrin (12766-04-5) Chlorpyrifos (12766-05-6) Cyfluthrin (12766-06-7) Deltamethrin (12766-07-8) Ethion (12766-08-9) Fenprophate (12766-09-0) Fenpyroximate (12766-10-1) Imidacloprid (12766-11-2) Permethrin (12766-12-3)</p> <p>Cal # 12767: Oregon Pesticide Standard P2 (12 compounds)</p> <p>Acetamiprid (12767-01-2) Acephate (12767-02-3) Acetamiprid (12767-03-4) Bifenthrin (12767-04-5) Chlorpyrifos (12767-05-6) Cyfluthrin (12767-06-7) Deltamethrin (12767-07-8) Ethion (12767-08-9) Fenprophate (12767-09-0) Fenpyroximate (12767-10-1) Imidacloprid (12767-11-2) Permethrin (12767-12-3)</p> <p>Cal # 12768: Oregon Pesticide Standard P3 (12 compounds)</p> <p>Abamectin (12768-01-2) Acephate (12768-02-3) Acetamiprid (12768-03-4) Bifenthrin (12768-04-5) Chlorpyrifos (12768-05-6) Cyfluthrin (12768-06-7) Deltamethrin (12768-07-8) Ethion (12768-08-9) Fenprophate (12768-09-0) Fenpyroximate (12768-10-1) Imidacloprid (12768-11-2) Permethrin (12768-12-3)</p> <p>Cal # 12769: Oregon Pesticide Standard P4 (12 compounds)</p> <p>Abamectin (12769-01-2) Acephate (12769-02-3) Acetamiprid (12769-03-4) Bifenthrin (12769-04-5) Chlorpyrifos (12769-05-6) Cyfluthrin (12769-06-7) Deltamethrin (12769-07-8) Ethion (12769-08-9) Fenprophate (12769-09-0) Fenpyroximate (12769-10-1) Imidacloprid (12769-11-2) Permethrin (12769-12-3)</p>	<p>Cal # 12770: Oregon Pesticide Standard P5 (12 compounds)</p> <p>Abamectin (12770-01-2) Acephate (12770-02-3) Acetamiprid (12770-03-4) Bifenthrin (12770-04-5) Chlorpyrifos (12770-05-6) Cyfluthrin (12770-06-7) Deltamethrin (12770-07-8) Ethion (12770-08-9) Fenprophate (12770-09-0) Fenpyroximate (12770-10-1) Imidacloprid (12770-11-2) Permethrin (12770-12-3)</p> <p>Cal # 12771: Oregon Pesticide Standard P6 (12 compounds)</p> <p>Abamectin (12771-01-2) Acephate (12771-02-3) Acetamiprid (12771-03-4) Bifenthrin (12771-04-5) Chlorpyrifos (12771-05-6) Cyfluthrin (12771-06-7) Deltamethrin (12771-07-8) Ethion (12771-08-9) Fenprophate (12771-09-0) Fenpyroximate (12771-10-1) Imidacloprid (12771-11-2) Permethrin (12771-12-3)</p> <p>Cal # 12772: Oregon Pesticide Standard P7 (12 compounds)</p> <p>Abamectin (12772-01-2) Acephate (12772-02-3) Acetamiprid (12772-03-4) Bifenthrin (12772-04-5) Chlorpyrifos (12772-05-6) Cyfluthrin (12772-06-7) Deltamethrin (12772-07-8) Ethion (12772-08-9) Fenprophate (12772-09-0) Fenpyroximate (12772-10-1) Imidacloprid (12772-11-2) Permethrin (12772-12-3)</p> <p>Cal # 12773: Oregon Pesticide Standard P8 (12 compounds)</p> <p>Abamectin (12773-01-2) Acephate (12773-02-3) Acetamiprid (12773-03-4) Bifenthrin (12773-04-5) Chlorpyrifos (12773-05-6) Cyfluthrin (12773-06-7) Deltamethrin (12773-07-8) Ethion (12773-08-9) Fenprophate (12773-09-0) Fenpyroximate (12773-10-1) Imidacloprid (12773-11-2) Permethrin (12773-12-3)</p>	<p>Cal # 12774: Oregon Pesticide Standard P9 (12 compounds)</p> <p>Abamectin (12774-01-2) Acephate (12774-02-3) Acetamiprid (12774-03-4) Bifenthrin (12774-04-5) Chlorpyrifos (12774-05-6) Cyfluthrin (12774-06-7) Deltamethrin (12774-07-8) Ethion (12774-08-9) Fenprophate (12774-09-0) Fenpyroximate (12774-10-1) Imidacloprid (12774-11-2) Permethrin (12774-12-3)</p> <p>Cal # 12775: Oregon Pesticide Standard P10 (12 compounds)</p> <p>Abamectin (12775-01-2) Acephate (12775-02-3) Acetamiprid (12775-03-4) Bifenthrin (12775-04-5) Chlorpyrifos (12775-05-6) Cyfluthrin (12775-06-7) Deltamethrin (12775-07-8) Ethion (12775-08-9) Fenprophate (12775-09-0) Fenpyroximate (12775-10-1) Imidacloprid (12775-11-2) Permethrin (12775-12-3)</p> <p>Cal # 12776: Oregon Pesticide Standard P11 (12 compounds)</p> <p>Abamectin (12776-01-2) Acephate (12776-02-3) Acetamiprid (12776-03-4) Bifenthrin (12776-04-5) Chlorpyrifos (12776-05-6) Cyfluthrin (12776-06-7) Deltamethrin (12776-07-8) Ethion (12776-08-9) Fenprophate (12776-09-0) Fenpyroximate (12776-10-1) Imidacloprid (12776-11-2) Permethrin (12776-12-3)</p> <p>Cal # 12777: Oregon Pesticide Standard P12 (12 compounds)</p> <p>Abamectin (12777-01-2) Acephate (12777-02-3) Acetamiprid (12777-03-4) Bifenthrin (12777-04-5) Chlorpyrifos (12777-05-6) Cyfluthrin (12777-06-7) Deltamethrin (12777-07-8) Ethion (12777-08-9) Fenprophate (12777-09-0) Fenpyroximate (12777-10-1) Imidacloprid (12777-11-2) Permethrin (12777-12-3)</p>
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Figure 5. Restek storage conditions

Corrective actions required to be completed ASAP listed below.

1. The laboratory shall immediately log this as a complaint and follow their complaint procedure QM-7.9 Complaints, Non-conforming work QM-7.10 Non-Conforming Work and Corrective action QM-8.7 Corrective Actions.
2. Due to the severity and public health implications for the many failures of the existing quality management system, the MRA is requesting a full regulatory audit conducted by the accrediting body or another 3rd party accreditor, the results of this audit shall be shared directly with the

MRA from the auditor at the same time they are sent to the facility. The MRA would like to be present for this audit, please notify us of the date and time.

3. The laboratory shall immediately institute a method for tracking samples in and out of incubators. Management shall review these with the temperature logs before results are reported to ensure accurate results in compliance with their QM-7.7 Ensuring the validity of results SOP.

4. The laboratory shall immediately institute continuous temperature monitoring for all incubators and update their current environmental monitoring SOP-QM - 6.3 Facilities and Environmental Conditions to include monitoring incubators.

5. The laboratory shall immediately revise current temperature logs to include the method specific ranges and corrective actions. At no such time should microbial results be reported if the temperature is outside of the acceptable validated ranges or if the samples have not been incubated within the acceptable timeframes found in the specific method package inserts.

6. The laboratory shall immediately assign a manager to review temperature logs, logs shall be signed and dated when reviewed, this should be added to the management review SOP QM-8.9 Management Reviews.

7. The laboratory shall compile a list of ALL nonconforming TYM samples and immediately provide the list to the agency. The laboratory should do a look back on all previously reported microbial testing and qualify results where they cannot demonstrate appropriate incubation time.

8. The laboratory shall provide all PCR run data directly from the instrument for all microbial methods from 8/10/2021 to current.

9. The laboratory shall immediately conduct a thorough root cause analysis for the nonconformances identified in this report and provide all documents to the MRA.

10. The laboratory shall immediately do a look back on samples in current inventory which have been passed for foreign matter and shall repeat the inspection following the approved SOP and additional training provided to staff from Claire Patterson during the Viridis North audit 10/27/2021, Michael Laframboise was present and should be lead on retraining all staff at both locations.

11. If non-conforming foreign matter samples are identified, the laboratory will update all test results in Metrc and provide a list of all samples.

12. Immediately Viridis laboratories needs to label marihuana product with the full Metrc tag number assigned in the statewide monitoring system. The only marihuana product onsite that does not require a Metrc tag number would be any compliantly obtained patient/caregiver material. This finding was observed during the December 2020 semi-annual inspection and has not been corrected, this needs to be corrected immediately.

13. The MRA is request all complaints and CAPAs for the last year to ensure there are no other issues that have been missed by the failures to the quality systems.

14. To protect the health of staff, the biochemical hood used for microbial testing will immediately need servicing to bring the expired certification current.

Schumacher, Brandon

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Thursday, November 18, 2021 7:32 PM
To: Kluytman, Julie (LARA); Michele Glinn; Patterson, Claire (LARA); Gregoire Michaud; Todd Welch; Russell, David; Michael LaFramboise; Mitchell, Desmond (LARA)
Subject: RE: Audit follow up

Julie,

This is so incredibly frustrating. I really thought we had turned a corner. Everyone was professional on the Teams meeting and we had what we thought was a productive discussion. But somehow we fell for yet another bait and switch. I promise not to ever surreptitiously record our conversations without your consent, but maybe we should agree to record future conversations so there are no misunderstandings? Because I'm fairly certain no one ever said that Viridis has to complete everything on a list we hadn't even seen yet before resuming testing. You said that there were "more details" on Claire's list that needed to be addressed sometime soon, but the bolded agenda items were all that need to happen before testing resumes. Your response below doesn't even make sense. The whole purpose of that Teams meeting was to go over what needs to happen before testing resumes, and your agenda says "The MRA would expect the items in bold would be corrected prior to resuming testing in those specific areas of concern." So why not share the longer list ahead of the meeting? I had to specifically request it and then you rushed us to end the meeting before we realized that the highlighted list is longer and includes some items that cannot possibly be completed in less than a few days at least. Again, you are effectively shutting down Viridis but deliberately not following the established procedures to do so.

Specifically, I am asking about the items that are impossible to complete by tomorrow morning and whether Viridis is approved to begin testing by showing significant compliance with your arbitrary list. As a regulatory agency, clear communication is paramount and you and your colleagues have purposely continued to speak in vague terms. The MRA represented yesterday that after the logs were approved that Viridis could start testing again. We spent the entire day yesterday going back-and-forth on that single point with no mention of these items other than stating we would have a meeting to discuss on Monday. This morning, you moved the goal posts and immediately put holds on all Viridis items despite your representations. Your actions not only to continue to severely damage Viridis, but also its customers, which has created chaos in the industry. These actions do not further the public health and safety in any way.

Kevin M. Blair

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O 517.377.0716
kblair@honigman.com

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Kevin,

The agenda states the bold items are a short summary of the corrective actions mentioned in the audit findings. I would not detail all the specific items needed from Claire's corrective action document in an agenda. This was explained in the meeting and the bold items correlate to the audit findings that were provided.

Julie Kluytman, Enforcement Division Director
Marijuana Regulatory Agency
kluytmanj@michigan.gov

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[Removed Kevin King]

Julie and Claire --

I believe you said and confirmed a few times on our Teams meeting just now that Viridis can resume microbial testing as soon as they complete the bolded items from Julie's agenda. Then the document Claire sent says everything highlighted has to be completed before testing resumes. That's exactly why I asked to see Claire's list before we logged off the meeting so there's no confusion about what needs to happen before testing resumes. One example is 4a that says Viridis must "[o]btain continuous, digital data monitoring devices for all incubators." Some of Viridis' incubators already have these, but some do not. We will order them tonight and pay for rush shipping, and provide proof of purchase. Can Viridis please resume testing once all the bolded items from Julie's agenda are completed as you repeatedly said on the Teams meeting, and we will provide proof that we're doing the rest of the highlighted list as fast as possible?

Here is a link to the devices we will order right now. Please confirm this is what you meant. Thank you.

https://www.avogadro-lab-supply.com/products/certified-digital-incubator-thermometer-50-to-70-c-cert-37%C2%BAC?variant=34426410959003¤cy=USD&utm_medium=product_sync&utm_source=google&utm_content=sag_organic&utm_campaign=sag_organic&gclid=Cj0KCQiAkNiMBhCxARIsAIDDKNWDLSAbGAHqWEc1r1Sc-8Lk10UeQbmR320lubhJumkHkMx2dRCSigaAliKEALw_wcB

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Sent: Thursday, November 18, 2021 8:39 PM
To: Blair, Kevin M.; Michele Glinn; Patterson, Claire (LARA); Gregoire Michaud; Todd Welch; Russell, David; Michael LaFramboise; Mitchell, Desmond (LARA)
Subject: RE: Audit follow up
Attachments: Viridis Agenda (002).docx

Kevin,

I am attaching the same agenda that was provided for the meeting, however I have "cut and pasted" directly from Claire's document where the items correlate to the agenda items as they were listed and I have highlighted the terms I used in the agenda so you can understand how I developed the agenda based on the more comprehensive document. To my knowledge, this is typically how agendas are created as they are intended to be lists of focal points for conversation and they don't typically include full conversations or documents.

I recall specifically addressing this in the meeting as Michele asked a question about the PCR and the TYM samples list because they were grouped together. I had placed them together for the agenda because I thought they were of the same topic but it was pointed out that there was some difference. Which is when we clarified again that Claire's document would provide more details and that I had placed these items together for the agenda.

Please let me know if there are any additional questions you have related to the requirements.

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Marijuana Regulatory Agency
kluytmanj@michigan.gov

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Subject: RE: Audit follow up

November 18, 2021

Agenda:

Meeting with Viridis and Viridis North

Purpose: Discuss Audit Finding Results and MRA Expectations

Audit Findings that require Corrective Action:

- Log this complaint
- Full audit by accrediting body and the MRA
- **The laboratory shall immediately institute a method for tracking samples in and out of ALL incubators.**
- **Temperature monitoring, revise temperature log, temperature log review**
- **Nonconforming TYM samples list and PCR run data provided to the agency**
- **Root cause analysis**
- Nonconforming foreign matter samples
- Label products appropriately
- Copy of all complaints sent to MRA

The items listed above are a short summary of the corrective actions mentioned in the audit findings. The MRA would expect the items in bold would be corrected prior to resuming testing in those specific areas of concern.

Schumacher, Brandon

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Subject: RE: Audit follow up

[Removed Kevin King]

Julie and Claire –

I believe you said and confirmed a few times on our Teams meeting just now that Viridis can resume microbial testing as soon as they complete the bolded items from Julie's agenda. Then the document Claire sent says everything highlighted has to be completed before testing resumes. That's exactly why I asked to see Claire's list before we logged off the meeting so there's no confusion about what needs to happen before testing resumes. One example is 4a that says Viridis must "[o]btain continuous, digital data monitoring devices for all incubators." Some of Viridis' incubators already have these, but some do not. We will order them tonight and pay for rush shipping, and provide proof of purchase. Can Viridis please resume testing once all the bolded items from Julie's agenda are completed as you repeatedly said on the Teams meeting, and we will provide proof that we're doing the rest of the highlighted list as fast as possible?

Here is a link to the devices we will order right now. Please confirm this is what you meant. Thank you.

https://www.avogadro-lab-supply.com/products/certified-digital-incubator-thermometer-50-to-70-c-cert-37%C2%BAc?variant=34426410959003¤cy=USD&utm_medium=product_sync&utm_source=google&utm_content=sag_organic&utm_campaign=sag_organic&gclid=Cj0KCQiAkNiMBhCxARIsAIDDKNWDLSAbGAHqWEc1r1Sc-8Lk10UeQbmR320lubhJumkHkMx2dRCSigaAliKEALw_wcB

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

From: Michele Glinn <mglinn@viridisgrp.com>
Sent: Thursday, November 18, 2021 4:21 PM
To: Blair, Kevin M. <KBlair@honigman.com>
Subject: Fw: Audit follow up

[EXTERNAL EMAIL]

See below.

Best Regards,

Michele A. Glinn, PhD, F-ABFT
Chief Science Officer/Founder
E: mglinn@viridisgrp.com



From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Thursday, November 18, 2021 4:16 PM
To: Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>; Todd Welch <twelch@viridisgrp.com>; Kevin King <kevin@dragonflymichigan.com>; drussell@fosterswift.com <drussell@fosterswift.com>; Michael LaFramboise <miaframboise@viridisgrp.com>
Cc: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>
Subject: Audit follow up

Please see attached.

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

(517) 230-2097
PattersonC8@michigan.gov
www.michigan.gov/MRA



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This e-mail may contain confidential or privileged information. If you are not the intended recipient, please delete it and notify the sender of the error.

Schumacher, Brandon

From: Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>
Sent: Thursday, November 18, 2021 5:39 PM
To: Blair, Kevin M.; Michele Glinn; Patterson, Claire (LARA); Gregoire Michaud; Todd Welch; Russell, David; Michael LaFramboise; Mitchell, Desmond (LARA)
Subject: RE: Audit follow up

Kevin,

The agenda states the bold items are a short summary of the corrective actions mentioned in the audit findings. I would not detail all the specific items needed from Claire's corrective action document in an agenda. This was explained in the meeting and the bold items correlate to the audit findings that were provided.

Julie Kluytman, Enforcement Division Director
Marijuana Regulatory Agency
kluytmanj@michigan.gov

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Thursday, November 18, 2021 5:12 PM
To: Michele Glinn <mglinn@viridisgrp.com>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Todd Welch <twelch@viridisgrp.com>; drussell@fosterswift.com; Michael LaFramboise <mlaframboise@viridisgrp.com>; Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Subject: RE: Audit follow up

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[Removed Kevin King]

Julie and Claire –

I believe you said and confirmed a few times on our Teams meeting just now that Viridis can resume microbial testing as soon as they complete the bolded items from Julie's agenda. Then the document Claire sent says everything highlighted has to be completed before testing resumes. That's exactly why I asked to see Claire's list before we logged off the meeting so there's no confusion about what needs to happen before testing resumes. One example is 4a that says Viridis must "[o]btain continuous, digital data monitoring devices for all incubators." Some of Viridis' incubators already have these, but some do not. We will order them tonight and pay for rush shipping, and provide proof of purchase. Can Viridis please resume testing once all the bolded items from Julie's agenda are completed as you repeatedly said on the Teams meeting, and we will provide proof that we're doing the rest of the highlighted list as fast as possible?

Here is a link to the devices we will order right now. Please confirm this is what you meant. Thank you.

https://www.avogadro-lab-supply.com/products/certified-digital-incubator-thermometer-50-to-70-c-cert-37%C2%BAC?variant=34426410959003¤cy=USD&utm_medium=product_sync&utm_source=google&utm_content=sag_organic&utm_campaign=sag_organic&gclid=Cj0KCQIAkNiMBhCxARIsAIDDKNWDLSAbGAHqW_Ec1r1Sc-8Lk10UeQbmR320lubhJumkHkMx2dRCSigaAliKEALw_wcB

Schumacher, Brandon

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Thursday, November 18, 2021 7:32 PM
To: Kluytman, Julie (LARA); Michele Glinn; Patterson, Claire (LARA); Gregoire Michaud; Todd Welch; Russell, David; Michael LaFramboise; Mitchell, Desmond (LARA)
Subject: RE: Audit follow up

Julie,

This is so incredibly frustrating. I really thought we had turned a corner. Everyone was professional on the Teams meeting and we had what we thought was a productive discussion. But somehow we fell for yet another bait and switch. I promise not to ever surreptitiously record our conversations without your consent, but maybe we should agree to record future conversations so there are no misunderstandings? Because I'm fairly certain no one ever said that Viridis has to complete everything on a list we hadn't even seen yet before resuming testing. You said that there were "more details" on Claire's list that needed to be addressed sometime soon, but the bolded agenda items were all that need to happen before testing resumes. Your response below doesn't even make sense. The whole purpose of that Teams meeting was to go over what needs to happen before testing resumes, and your agenda says "The MRA would expect the items in bold would be corrected prior to resuming testing in those specific areas of concern." So why not share the longer list ahead of the meeting? I had to specifically request it and then you rushed us to end the meeting before we realized that the highlighted list is longer and includes some items that cannot possibly be completed in less than a few days at least. Again, you are effectively shutting down Viridis but deliberately not following the established procedures to do so.

Specifically, I am asking about the items that are impossible to complete by tomorrow morning and whether Viridis is approved to begin testing by showing significant compliance with your arbitrary list. As a regulatory agency, clear communication is paramount and you and your colleagues have purposely continued to speak in vague terms. The MRA represented yesterday that after the logs were approved that Viridis could start testing again. We spent the entire day yesterday going back-and-forth on that single point with no mention of these items other than stating we would have a meeting to discuss on Monday. This morning, you moved the goal posts and immediately put holds on all Viridis items despite your representations. Your actions not only to continue to severely damage Viridis, but also its customers, which has created chaos in the industry. These actions do not further the public health and safety in any way.

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

From: Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>
Sent: Thursday, November 18, 2021 5:39 PM
To: Blair, Kevin M. <KBlair@honigman.com>; Michele Glinn <mglinn@viridisgrp.com>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Todd Welch <twelch@viridisgrp.com>; drussell@fosterswift.com; Michael LaFramboise <miaframboise@viridisgrp.com>; Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>
Subject: RE: Audit follow up

[EXTERNAL EMAIL]

Kevin,

The agenda states the bold items are a short summary of the corrective actions mentioned in the audit findings. I would not detail all the specific items needed from Claire's corrective action document in an agenda. This was explained in the meeting and the bold items correlate to the audit findings that were provided.

Julie Kluytman, Enforcement Division Director
Marijuana Regulatory Agency
kluytmanj@michigan.gov

From: Blair, Kevin M. <KBlair@honigman.com>

Sent: Thursday, November 18, 2021 5:12 PM

To: Michele Glinn <mglinn@viridisgrp.com>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Todd Welch <twelch@viridisgrp.com>; drussell@fosterswift.com; Michael LaFramboise <mmlaframboise@viridisgrp.com>; Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>

Subject: RE: Audit follow up

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[Removed Kevin King]

Julie and Claire –

I believe you said and confirmed a few times on our Teams meeting just now that Viridis can resume microbial testing as soon as they complete the bolded items from Julie's agenda. Then the document Claire sent says everything highlighted has to be completed before testing resumes. That's exactly why I asked to see Claire's list before we logged off the meeting so there's no confusion about what needs to happen before testing resumes. One example is 4a that says Viridis must "[o]btain continuous, digital data monitoring devices for all incubators." Some of Viridis' incubators already have these, but some do not. We will order them tonight and pay for rush shipping, and provide proof of purchase. Can Viridis please resume testing once all the bolded items from Julie's agenda are completed as you repeatedly said on the Teams meeting, and we will provide proof that we're doing the rest of the highlighted list as fast as possible?

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https://www.avogadro-lab-supply.com/products/certified-digital-incubator-thermometer-50-to-70-c-cert-37%C2%BAC?variant=34426410959003¤cy=USD&utm_medium=product_sync&utm_source=google&utm_content=sag_organic&utm_campaign=sag_organic&gclid=Cj0KCQIAkNiMBhCxARIsAIDDKNWDLSAbGAHqWEc1r1Sc-8Lk10UeQbmR320lubhJumkHkMx2dRCSigaAliKEALw_wcB

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716

From: Kevin King [<mailto:kevin@dragonflymichigan.com>]

Sent: Thursday, November 18, 2021 4:19 PM

To: Patterson, Claire (LARA)

Cc: Gregoire Michaud; Michele Glinn; Todd Welch; Russell, David; Michael LaFramboise; Mitchell, Desmond (LARA); Kluytman, Julie (LARA)

Subject: Re: Audit follow up

I believe this was sent to me in error. Is that confirmed?

Regards,

Kevin King

Director of Laboratory Operations

Dragonfly Kitchen II Inc | 26980 County Road 215 | Bangor, MI 49013

C: 708.846.4272

www.dragonflymichigan.com

Kevin@dragonflymichigan.com

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On Thu, Nov 18, 2021 at 4:16 PM Patterson, Claire (LARA) <PattersonC8@michigan.gov> wrote:

Please see attached.

Claire Patterson

Manager, Scientific & Legal Section

Enforcement Division

Marijuana Regulatory Agency

(517) 230-2097

PattersonC8@michigan.gov

www.michigan.gov/MRA



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Schumacher, Brandon

From: Schumacher, Brandon
Sent: Monday, November 22, 2021 1:29 PM
To: 'Mains, Douglas E.'; Blair, Kevin M.; Garrison, Emily E.; Russell, David
Subject: FW: Follow up & Summary of test results & Draft Recall Bulletin

Brandon M. H. Schumacher
Attorney
Foster Swift Collins & Smith PC
313 South Washington Square
Lansing, MI 48933-2193
Office Direct: 517.371.8255
Cell: 517.420.5741
Assistant: Sharla Clements: 517.371.8188
Fax: 517.367.7167
bschumacher@fosterswift.com
www.fosterswift.com

FOSTER SWIFT

From: Russell, David
Sent: Wednesday, November 17, 2021 4:46 PM
To: Schumacher, Brandon
Subject: FW: Follow up & Summary of test results & Draft Recall Bulletin

David R. Russell
Attorney
Foster Swift Collins & Smith PC
313 S. Washington Square
Lansing, MI 48933
Phone: 517.371.8150
Fax: 517.367.7150
drussell@fosterswift.com
www.fosterswift.com

FOSTER SWIFT

From: MCINTYRE Maria [<mailto:maria.mcintyre@biomerieux.com>]
Sent: Wednesday, November 17, 2021 4:03 PM
To: Russell, David; 'Mitchell, Desmond (LARA)'; Blair, Kevin M.
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully, Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotek.com; MILLS John
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

Adding John Mills to the conversation.

1. Methods utilized have AOAC approval. This data collection usually includes robustness data that may or may not be a change in temperature. Please know, we are working to confirm if this data is available from

the work for AOAC. This may take time to capture as I am collaborating with John Mills- Scientific Affairs Manager and Dr. Ron Johnson- former AOAC President.

2. ISO 17025 accreditation impacts the discussion as ISO sets the benchmark for the quality standards within accredited laboratories. If a recall is generated under these circumstances it's a reflection of a gap in ISO accreditation and does not relate to AOAC or the method itself. The lab has completed training on the method reflected in the training certificates and demonstrated via the ISO 17025 accreditation process.
3. When there is uncertainty in results either retesting or confirmation testing generally holds greater value than a multi-lab study. In such a study, there are many variable in the equation leading to variability.
4. The iso files have been reviewed and the assay appears to be running properly. The files have been transferred to the R&D team who created this assay for a 2nd opinion and to determine if other areas require addressing.

Kind regards,
Maria

Maria McIntyre
425-275-8013

From: Russell, David <DRussell@fosterswift.com>

Sent: Wednesday, November 17, 2021 11:59 AM

To: 'Mitchell, Desmond (LARA)' <MitchellD6@michigan.gov>; Blair, Kevin M. <KBlair@honigman.com>

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotech.com; MCINTYRE Maria <maria.mcintyre@biomerieux.com>

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Desmond – I would ask for just a few more minutes. We have spoken with both Ms. McIntyre and Mr. Bird and they are working on sending those now. Thanks.

David R. Russell
Attorney
Foster Swift Collins & Smith PC
313 S. Washington Square
Lansing, MI 48933
Phone: 517.371.8150
Fax: 517.367.7150
drussell@fosterswift.com
www.fosterswift.com

FOSTER SWIFT

From: Mitchell, Desmond (LARA) [<mailto:MitchellD6@michigan.gov>]

Sent: Wednesday, November 17, 2021 1:48 PM

To: Blair, Kevin M.; Russell, David

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully, Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotech.com

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

Kevin,

I can't wait until tomorrow. I'll give you until 3 pm. Also, you're aware that the absence of the logs is only part of the issue.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchelld6@michigan.gov

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Wednesday, November 17, 2021 1:39 PM
To: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Russell, David <DRussell@fosterswift.com>
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Desmond --

You said repeatedly yesterday that the absence of logs alone would not justify a recall. You pointed to the test results as the primary basis for warranting a recall. But recall that there are no test results at all related to Viridis North's results. At a minimum, Viridis North should be carved out of this recall. They are a separate licensee, with different ownership, and there is no reason they should get swept into this crippling recall just because their name also includes the word "Viridis."

Also, we are doing all we can to reconnect with Mr. Bird and Ms. McIntyre to get statements from them. They are tied up in other meetings and we haven't been able to reach them, but again, Mr. Bird has been copied on all these emails and we're confident that we have not misrepresented his views. We are asking that you give us until 8:30 tomorrow to get those statements. The stakes here couldn't be any higher, and we urge you not to rush forward with this simply because these folks weren't instantaneously available to drop everything and write statements.

Kevin

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

From: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>
Sent: Wednesday, November 17, 2021 12:52 PM
To: Russell, David <DRussell@fosterswift.com>; Blair, Kevin M. <KBlair@honigman.com>
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

[EXTERNAL EMAIL]

Have them submit those exact statements to me in writing and I'll consider discussing it further.

Also, that's not evidence my staff leaked it.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchellD6@michigan.gov

From: Russell, David <DRussell@fosterswift.com>
Sent: Wednesday, November 17, 2021 12:45 PM
To: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Blair, Kevin M. <KBlair@honigman.com>
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Desmond,

I know Kevin is driving, and this is extremely important, so I want to respond immediately. We have Mr. Bird, copied on this e-mail, and Marie McIntyre from bioMeriux that support our position that this recall is not appropriate. We are not sure how there could be any other explanation than retaliation when you have Mr. Bird stating this recall is inappropriate and Ms. McIntyre from the manufacturer of the platform stating that these retests do not support your position and yet the MRA insists on moving forward. We would ask to at least have the opportunity to get everyone on a call to discuss. The stakes are way too big here to risk a miscommunication that you suggest in your e-mail below. Please remember that Mr. Bird has been copied on all of these e-mails. This will destroy Viridis.

We certainly have evidence that there are leaks. There are people that knew the August 10th start date from your recall notice, which is not public information, early this morning.

Please let me know if we can set up a call.

Dave

David R. Russell
Attorney
Foster Swift Collins & Smith PC
313 S. Washington Square
Lansing, MI 48933
Phone: 517.371.8150
Fax: 517.367.7150
drussell@fosterswift.com
www.fosterswift.com

FOSTER SWIFT

From: Mitchell, Desmond (LARA) [<mailto:MitchellD6@michigan.gov>]
Sent: Wednesday, November 17, 2021 12:24 PM
To: Blair, Kevin M.
Cc: Russell, David; gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully, Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotek.com
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

Kevin,

As I've repeatedly stated, no one at the MRA is angry with Viridis. We're just following through with our regulatory responsibilities.

As far as your allegation about staff leaking information regarding the recall, do you have any evidence to support it?

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchelld6@michigan.gov

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Wednesday, November 17, 2021 12:17 PM
To: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>
Cc: Russell, David <DRussell@fosterswift.com>; gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com
Subject: Re: Follow up & Summary of test results & Draft Recall Bulletin

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--

I'm begging you to please get on teams or phone to discuss and try and find a way for cooler heads to prevail. We truly believe this would be a huge mistake. It's one of the biggest recalls ever in the country based on the flimsiest of reasons.

Also, we've heard from countless people in the industry this morning that already know precise details about this recall. They didn't get that info from us so you have at least one staff member so happy about this recall that they're leaking it to the industry beforehand. That alone should give you pause and reconsider the clear biases of some of those who are trying to convince you that this is a safety issue.

Sent from my iPhone

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

On Nov 17, 2021, at 11:46 AM, Mitchell, Desmond (LARA) <MitchellD6@michigan.gov> wrote:

[EXTERNAL EMAIL]

Good Morning Dave,

Thank you for the feedback. Please note the following:

1. Claire also spoke to Mr. Bird and I don't believe your statements are a full and accurate representation of his point of view.
2. I'm not comfortable with your proposed revisions. I believe our initial draft provides a more accurate representation of the situation to the public and consumers. As a result, the attached bulletin is the one that will be issued today.
3. The investigation is still ongoing. As part of that investigation, we'll determine if the recall should be expanded as you've indicated. If it does, we'll expand the recall. However, as Kevin has pointed out before this is a public health and safety issue and we need to act on this as soon as possible. I believe there is currently sufficient evidence for us to proceed.
4. The MRA is also open to and believes it is necessary to continue to have discussions after the recall is issued and hopefully prevent something like this from happening in the future.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchelld6@michigan.gov

From: Russell, David <DRussell@fosterswift.com>
Sent: Wednesday, November 17, 2021 9:55 AM
To: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; KBlair@honigman.com
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA)

<KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; 'consulting@pmbbiotek.com' <consulting@pmbbiotek.com>
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Good morning, Desmond.

In conversations yesterday and today with Pat Bird, a consultant with the AOAC, Mr. Bird has confirmed to Viridis that not having sample incubation times tracked is not a divergence from the approved AOAC method. Further, Mr. Bird agreed that use of the 10 sample tests sent to five different laboratories is not an appropriate method to confirm Viridis' testing for Aspergillus and an improper reason to issue a recall. Additionally, Viridis has had conversations with Marie McIntyre from bioMeriux and she too has opined that the MRA's use of the 10 sample tests is not a proper way to confirm Viridis' retests. I have copied Pat Bird on this e-mail, so he can confirm our conversation if necessary or answer any questions that you may have. It is my understanding that Mr. Bird called Ms. Patterson this morning to discuss this matter and he has indicated a willingness to speak to you as well.

Notwithstanding the fact that Viridis strongly disagrees that any recall is appropriate, at your request, I'm attaching clean and redline versions of your proposed recall bulletin with our proposed changes. While we strongly disagree with your analysis and decision to issue this recall, we respectfully submit that if health and safety is truly your main concern, you can accomplish the exact same result without all the alarmist and defamatory language you included in the first draft. We also truly don't understand why the scope of this recall includes all products (except inhalable concentrates). The proposed recall would encompass approximately 64,489 lbs. of flower (not counting trim, concentrates, etc.) over this period and using the average retail price per lbs. would total \$229,645,329.

All of our discussions thus far have focused on aspergillus, and yet this recall is essentially saying you don't trust any test results at all from Viridis (even products that were tested only for terpenes, potency, or other tests that have nothing to do with aspergillus tests). Therefore, any recall should focus solely on aspergillus results. As we discussed yesterday, 8/10 has no logical connection to the aspergillus test issues, and if the absence of logs alone justifies a recall, this recall should cover everything Viridis has tested for aspergillus since 2019. If, on the other hand, the recall is based on the competitors' test results, then the earliest collection date is 9/13.

Second, we respectfully urge you again to reconsider. This is a truly unprecedented and illogical recall. When Iron Laboratories was caught red handed falsifying records and deceiving consumers about the presence of dangerous pesticides, the MRA said it "has not been made aware of any adverse product reactions in conjunction with product tested by Iron Laboratories and is not recalling any marijuana product at this time." In contrast here, Viridis has been performing these tests for two years with the MRA's full knowledge, the MRA has observed these tests countless times and never said a word about not having incubator timing logs until 10/26/21. As soon as the MRA raised this issue, Viridis agreed to begin keeping these logs. And even after the MRA first raised this on 10/26, you waited another 3 weeks to issue the recall. You said yesterday that you were waiting for test results, but Metrc shows that all but a few of the tests were completed by 11/1. It's hard to understand why the MRA waited 15 days to issue a recall if this was truly a health and safety issue. We also discussed yesterday

how four of the ten labs' results were consistent with Viridis' results, and yet it appears this recall is targeting Viridis only, and not those other labs. At a minimum, this should be a 3-lab recall since The Spot and Can-Lab both got the exact same result as Viridis (passed a sample with two consecutive negative tests after the sample was initially failed and not remediated). Also, we have been in contact with A2LA, AOAC, and bioMerieux, who are all reviewing the data and have expressed serious concerns about your purported basis for this recall. I urge you again to let Viridis re-test these samples, or have an independent third party re-test them, or do an inter-lab test, or a proficiency test, or whatever test you want. Rushing into this recall on such flimsy, ill-advised rationale would be a colossal mistake that would cripple Viridis' business, wreak havoc on the entire industry, and raise serious questions about the MRA's integrity overall.

Finally, while we are sincerely interested in having further discussions and exploring any possible alternatives to this recall, we just want to reiterate that we feel like you've backed Viridis into a corner here and if you issue this recall, they will have no choice but to issue a press release to set the record straight and try to mitigate the damage from this ill-advised and completely illogical recall. We sincerely hope that won't be necessary, but we honestly don't feel like we have any other choice at this point unless the MRA drops this recall threat and starts working with us collaboratively to address the substance of your concerns. (It is well documented that we have been trying to have that dialogue with your staff since August to no avail; instead, it seems some have been spending all their time determined to find any potential reason to justify a recall).

Thank you,

Dave

David R. Russell
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Fax: 517.367.7150
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From: Mitchell, Desmond (LARA) [<mailto:MitchellD6@michigan.gov>]
Sent: Tuesday, November 16, 2021 4:57 PM
To: KBlair@honigman.com
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Russell, David; Hunt-Scully, Risa (AG)
Subject: FW: Follow up & Summary of test results & Draft Recall Bulletin
Importance: High

Kevin,

- I apologize for the delay. I've attached the recall bulletin for your review. Please provide any feedback or suggested revisions by 10 am on 11/17/2021. We'll review any proposed revisions and let you know if they will be adopted.
- Please see Claire's responses to your questions below.

If you have any questions, let me know. Thank you.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchelld6@michigan.gov

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Tuesday, November 16, 2021 10:58 AM
To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>
Cc: Mitchell, Desmond (LARA) <Mitchelld6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; drussell@fosterswift.com
Subject: RE: Follow up & Summary of test results

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Thank you for correcting that. I mean that sincerely. I appreciate you taking the time to triple check and correct that info. I just want to note, though, that the stakes here couldn't be any bigger. We're talking about health and safety, and we're here on the precipice of an enormous potential recall (that would cripple Viridis and raise serious questions about the integrity of the entire process) and one of the key data points that got us here wasn't just wrong in the initial chart, you also confirmed it again this morning via email. It wasn't until the third check that mistake was finally realized.

Also, I think it's critical to consider how many of the tests corroborate Viridis's samples. Just based on the "pass" results alone, that's 4 out of ten that are consistent with Viridis's results (and several of the other 6 were tested by competitors who have publicly talked about trying to put Viridis out of business, so how do you account for that obvious bias?).

For the retests in question, and for the sake of this conversation, we will exclude the test performed by Infinite because that sample should have been passing. This sample may be viewed as a control, in this case, and should rightly be excluded from any further data analysis.

With all this considered:

- Viridis performed 8 retests and passed 100% of them, failing 0% of the retests.
- Of the additional 8 retests performed by 4 separate facilities, 6 failed. That leaves us with a 25% passing rate and a 75% failure rate. This level of uncertainty is enough cause for concern.
- Regardless of competition, all scientists should be well versed in the ethical conduct of research. If they are not, they also are aware that all raw data and all data, in fact, is subject to scrutiny by the agency. I have no concerns about bias as the licensees were not told that this investigation had anything to do with Viridis. All labs were simply directed to pick up samples from the lab and from the grow. This is commonplace in all investigations that require retesting and does not single out the lab in particular as being part of the investigation.

Further, if any of the "fail" or "set to fail" cells had any test(s) pass, that's very important information to consider. If there was one pass and one fail, I understand that would be a fail under the rules. But if you're truly making data-driven decisions here, there shouldn't be any hesitation to share the data with us. If there were no negative tests associated with the "fail" or "set to fail" samples, why wouldn't you tell us that? And if there were, we'd like to know how many.

- I am not entirely sure of what you are asking in the case. Aside from the error that was corrected for sample number ending in -1014, all results are correct.

- There is no additional information to be provided here.
- If you are referring to an overall analysis of data, Viridis and Viridis North provide the 1st and 3rd most tests to the regulated market in Michigan.
- During this time of year, in particular, Aspergillus is incredibly common, with the average percentage of total flower packages tested resulting in an Aspergillus failure 9.43% of the time.
- The mean value on this data set is 7.42%.
- Despite the fact that Viridis and Viridis North perform the 1st and 3rd most tests in the state, they are only reporting aspergillus failures for 0.78% and 4.9% of those samples, respectively. Given that they fall well under both the median and average values for reporting, the data is considered anomalous and is being treated as such.

Kevin M. Blair

HONIGMAN LLP

O 517.377.0716
kblair@honigman.com

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Tuesday, November 16, 2021 10:27 AM
To: Blair, Kevin M. <KBlair@honigman.com>; Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>
Cc: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; drussell@fosterswift.com
Subject: RE: Follow up & Summary of test results

[EXTERNAL EMAIL]

All,

Upon confirmation with COAs and data, I have updated a sample from The Spott to reflect a passing status for package:

1A4050300009155000001014

Please note that package:

1A4050300009155000001015

Is set as fail, and the overall retest result is set to fail.

Thank you,

Claire Patterson

Manager, Scientific & Legal Section
 Enforcement Division
 Marijuana Regulatory Agency

(517) 230-2097

PattersonC8@michigan.gov
www.michigan.gov/MRA

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From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Tuesday, November 16, 2021 10:00 AM
To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>
Cc: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; drussell@fosterswift.com
Subject: RE: Follow up & Summary of test results

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Claire –

Have you had a chance yet to check whether the first sample retested by The Spott (ending in 1014) was a pass or fail? Your chart shows a fail, but it appears in METRC as a pass.

Also, is there a difference on your chart between the cells that say “fail” vs “set to fail”? For example, does “fail” mean they had two positive tests whereas “set to fail” might mean they had one positive and one negative? If so, that is important information and context for us and Desmond to know (i.e., some of these samples may have tested negative 3 out of 4 times).

Kevin M. Blair

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O 517.377.0716
kblair@honigman.com

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Monday, November 15, 2021 1:38 PM
To: Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>; Blair, Kevin M. <KBlair@honigman.com>
Cc: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>
Subject: Follow up & Summary of test results

[EXTERNAL EMAIL]

Hi Greg,

As discussed on our call, I am attaching a summary of the test results for the tests in question.

All the best,

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

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Schumacher, Brandon

From: Schumacher, Brandon
Sent: Monday, November 22, 2021 1:29 PM
To: 'Mains, Douglas E.'; Garrison, Emily E.; Blair, Kevin M.; Russell, David
Subject: FW: Follow up & Summary of test results & Draft Recall Bulletin

Brandon M. H. Schumacher
Attorney
Foster Swift Collins & Smith PC
313 South Washington Square
Lansing, MI 48933-2193
Office Direct: 517.371.8255
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FOSTER SWIFT

From: Russell, David
Sent: Wednesday, November 17, 2021 4:46 PM
To: Schumacher, Brandon
Subject: FW: Follow up & Summary of test results & Draft Recall Bulletin

David R. Russell
Attorney
Foster Swift Collins & Smith PC
313 S. Washington Square
Lansing, MI 48933
Phone: 517.371.8150
Fax: 517.367.7150
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FOSTER SWIFT

From: Russell, David
Sent: Wednesday, November 17, 2021 4:43 PM
To: 'Mitchell, Desmond (LARA)'; MCINTYRE Maria; Blair, Kevin M.
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully, Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotek.com; MILLS John
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

Once you have issued the recall the irreparable damage is done to this business. You have two subject matter experts opining that the recall is not appropriate based on your "tests".

David R. Russell

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FOSTER SWIFT

From: Mitchell, Desmond (LARA) [mailto:MITCHELLD6@michigan.gov]
Sent: Wednesday, November 17, 2021 4:36 PM
To: Russell, David; MCINTYRE Maria; Blair, Kevin M.
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully, Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotek.com; MILLS John
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

We've discussed it enough. We can continue to discuss it as the investigation continues. Also, the statements submitted do not provide any evidence that would support a delay in issuing a recall.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchellD6@michigan.gov

From: Russell, David <DRussell@fosterswift.com>
Sent: Wednesday, November 17, 2021 4:28 PM
To: Mitchell, Desmond (LARA) <MITCHELLD6@michigan.gov>; MCINTYRE Maria <maria.mcintyre@biomerieux.com>; Blair, Kevin M. <KBlair@honigman.com>
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com; MILLS John <John.MILLS@biomerieux.com>
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Desmond – You stated earlier in your e-mail that if you were provided with the requested information that you would consider discussing it further. We have provided the information as requested that clearly shows that your tests do not warrant a recall. This is clearly not a health and safety issue. Please schedule a phone call to discuss with subject matter experts. Dave

David R. Russell

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FOSTER SWIFT

From: Mitchell, Desmond (LARA) [<mailto:MitchellD6@michigan.gov>]
Sent: Wednesday, November 17, 2021 4:23 PM
To: MCINTYRE Maria; Russell, David; Blair, Kevin M.
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully, Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotek.com; MILLS John
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

All,

I appreciate the additional information, but no information has been provided that would prevent the recall. It will be issued today.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchelld6@michigan.gov

From: MCINTYRE Maria <maria.mcintyre@biomerieux.com>
Sent: Wednesday, November 17, 2021 4:03 PM
To: Russell, David <DRussell@fosterswift.com>; Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Blair, Kevin M. <KBlair@honigman.com>
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com; MILLS John <John.MILLS@biomerieux.com>
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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--

Adding John Mills to the conversation.

1. Methods utilized have AOAC approval. This data collection usually includes robustness data that may or may not be a change in temperature. Please know, we are working to confirm if this data is available from the work for AOAC. This may take time to capture as I am collaborating with John Mills- Scientific Affairs Manager and Dr. Ron Johnson- former AOAC President.

2. ISO 17025 accreditation impacts the discussion as ISO sets the benchmark for the quality standards within accredited laboratories. If a recall is generated under these circumstances it's a reflection of a gap in ISO accreditation and does not relate to AOAC or the method itself. The lab has completed training on the method reflected in the training certificates and demonstrated via the ISO 17025 accreditation process.
3. When there is uncertainty in results either retesting or confirmation testing generally holds greater value than a multi-lab study. In such a study, there are many variable in the equation leading to variability.
4. The iso files have been reviewed and the assay appears to be running properly. The files have been transferred to the R&D team who created this assay for a 2nd opinion and to determine if other areas require addressing.

Kind regards,
Maria

Maria McIntyre
425-275-8013

From: Russell, David <DRussell@fosterswift.com>
Sent: Wednesday, November 17, 2021 11:59 AM
To: 'Mitchell, Desmond (LARA)' <MitchellD6@michigan.gov>; Blair, Kevin M. <KBlair@honigman.com>
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com; MCINTYRE Maria <maria.mcintyre@biomerieux.com>
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Desmond – I would ask for just a few more minutes. We have spoken with both Ms. McIntyre and Mr. Bird and they are working on sending those now. Thanks.

David R. Russell
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FOSTER SWIFT

From: Mitchell, Desmond (LARA) [<mailto:MitchellD6@michigan.gov>]
Sent: Wednesday, November 17, 2021 1:48 PM
To: Blair, Kevin M.; Russell, David
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully, Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotek.com
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

Kevin,

I can't wait until tomorrow. I'll give you until 3 pm. Also, you're aware that the absence of the logs is only part of the issue.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchelld6@michigan.gov

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Wednesday, November 17, 2021 1:39 PM
To: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Russell, David <DRussell@fosterswift.com>
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotech.com
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Desmond –

You said repeatedly yesterday that the absence of logs alone would not justify a recall. You pointed to the test results as the primary basis for warranting a recall. But recall that there are no test results at all related to Viridis North's results. At a minimum, Viridis North should be carved out of this recall. They are a separate licensee, with different ownership, and there is no reason they should get swept into this crippling recall just because their name also includes the word "Viridis."

Also, we are doing all we can to reconnect with Mr. Bird and Ms. McIntyre to get statements from them. They are tied up in other meetings and we haven't been able to reach them, but again, Mr. Bird has been copied on all these emails and we're confident that we have not misrepresented his views. We are asking that you give us until 8:30 tomorrow to get those statements. The stakes here couldn't be any higher, and we urge you not to rush forward with this simply because these folks weren't instantaneously available to drop everything and write statements.

Kevin

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

From: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>
Sent: Wednesday, November 17, 2021 12:52 PM
To: Russell, David <DRussell@fosterswift.com>; Blair, Kevin M. <KBlair@honigman.com>

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

[EXTERNAL EMAIL]

Have them submit those exact statements to me in writing and I'll consider discussing it further.

Also, that's not evidence my staff leaked it.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchelld6@michigan.gov

From: Russell, David <DRussell@fosterswift.com>
Sent: Wednesday, November 17, 2021 12:45 PM
To: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Blair, Kevin M. <KBlair@honigman.com>
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Desmond,

I know Kevin is driving, and this is extremely important, so I want to respond immediately. We have Mr. Bird, copied on this e-mail, and Marie McIntyre from bioMeriux that support our position that this recall is not appropriate. We are not sure how there could be any other explanation than retaliation when you have Mr. Bird stating this recall is inappropriate and Ms. McIntyre from the manufacturer of the platform stating that these retests do not support your position and yet the MRA insists on moving forward. We would ask to at least have the opportunity to get everyone on a call to discuss. The stakes are way too big here to risk a miscommunication that you suggest in your e-mail below. Please remember that Mr. Bird has been copied on all of these e-mails. This will destroy Viridis.

We certainly have evidence that there are leaks. There a people that knew the August 10th start date from your recall notice, which is not public information, early this morning.

Please let me know if we can set up a call.

Dave

David R. Russell
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Lansing, MI 48933
Phone: 517.371.8150
Fax: 517.367.7150
drussell@fosterswift.com
www.fosterswift.com

FOSTER SWIFT

From: Mitchell, Desmond (LARA) [<mailto:MitchellD6@michigan.gov>]
Sent: Wednesday, November 17, 2021 12:24 PM
To: Blair, Kevin M.
Cc: Russell, David; gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully, Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotek.com
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

Kevin,

As I've repeatedly stated, no one at the MRA is angry with Viridis. We're just following through with our regulatory responsibilities.

As far as your allegation about staff leaking information regarding the recall, do you have any evidence to support it?

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchelld6@michigan.gov

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Wednesday, November 17, 2021 12:17 PM
To: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>
Cc: Russell, David <DRussell@fosterswift.com>; gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com
Subject: Re: Follow up & Summary of test results & Draft Recall Bulletin

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--

I'm begging you to please get on teams or phone to discuss and try and find a way for cooler heads to prevail. We truly believe this would be a huge mistake. It's one of the biggest recalls ever in the country based on the flimsiest of reasons.

Also, we've heard from countless people in the industry this morning that already know precise details about this recall. They didn't get that info from us so you have at least one staff member so happy about this recall that they're leaking it to the industry beforehand. That alone should give you pause and reconsider the clear biases of some of those who are trying to convince you that this is a safety issue.

Sent from my iPhone

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

On Nov 17, 2021, at 11:46 AM, Mitchell, Desmond (LARA) <MitchellD6@michigan.gov> wrote:

[EXTERNAL EMAIL]

Good Morning Dave,

Thank you for the feedback. Please note the following:

1. Claire also spoke to Mr. Bird and I don't believe your statements are a full and accurate representation of his point of view.
2. I'm not comfortable with your proposed revisions. I believe our initial draft provides a more accurate representation of the situation to the public and consumers. As a result, the attached bulletin is the one that will be issued today.
3. The investigation is still ongoing. As part of that investigation, we'll determine if the recall should be expanded as you've indicated. If it does, we'll expand the recall. However, as Kevin has pointed out before this is a public health and safety issue and we need to act on this as soon as possible. I believe there is currently sufficient evidence for us to proceed.
4. The MRA is also open to and believes it is necessary to continue to have discussions after the recall is issued and hopefully prevent something like this from happening in the future.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchelld6@michigan.gov

From: Russell, David <DRussell@fosterswift.com>
Sent: Wednesday, November 17, 2021 9:55 AM
To: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; KBlair@honigman.com
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; 'consulting@pmbbiotek.com' <consulting@pmbbiotek.com>
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Good morning, Desmond.

In conversations yesterday and today with Pat Bird, a consultant with the AOAC, Mr. Bird has confirmed to Viridis that not having sample incubation times tracked is not a divergence from the approved AOAC method. Further, Mr. Bird agreed that use of the 10 sample tests sent to five different laboratories is not an appropriate method to confirm Viridis' testing for *Apergillus* and an improper reason to issue a recall. Additionally, Viridis has had conversations with Marie McIntyre from bioMeriux and she too has opined that the MRA's use of the 10 sample tests is not a proper way to confirm Viridis' retests. I have copied Pat Bird on this e-mail, so he can confirm our conversation if necessary or answer any questions that you may have. It is my understanding that Mr. Bird called Ms. Patterson this morning to discuss this matter and he has indicated a willingness to speak to you as well.

Notwithstanding the fact that Viridis strongly disagrees that any recall is appropriate, at your request, I'm attaching clean and redline versions of your proposed recall bulletin with our proposed changes. While we strongly disagree with your analysis and decision to issue this recall, we respectfully submit that if health and safety is truly your main concern, you can accomplish the exact same result without all the alarmist and defamatory language you included in the first draft. We also truly don't understand why the scope of this recall includes all products (except inhalable concentrates). The proposed recall would encompass approximately 64,489 lbs. of flower (not counting trim, concentrates, etc.) over this period and using the average retail price per lbs. would total \$229,645,329.

All of our discussions thus far have focused on *aspergillus*, and yet this recall is essentially saying you don't trust any test results at all from Viridis (even products that were tested only for terpenes, potency, or other tests that have nothing to do with *aspergillus* tests). Therefore, any recall should focus solely on *aspergillus* results. As we discussed yesterday, 8/10 has no logical connection to the *aspergillus* test issues, and if the absence of logs alone justifies a recall, this recall should cover everything Viridis has tested for *aspergillus* since 2019. If, on the other hand, the recall is based on the competitors' test results, then the earliest collection date is 9/13.

Second, we respectfully urge you again to reconsider. This is a truly unprecedented and illogical recall. When Iron Laboratories was caught red handed falsifying records and deceiving consumers about the presence of dangerous pesticides, the MRA said it "has not been made aware of any adverse product reactions in conjunction with product tested by Iron Laboratories and is not recalling any marijuana product at this time." In contrast here, Viridis has been performing these tests for two years with the MRA's full knowledge, the MRA has observed these tests countless times and never said a word about not having incubator timing logs until 10/26/21. As soon as the MRA raised this issue, Viridis agreed to begin keeping these logs. And even after the MRA first raised this on 10/26, you waited another 3 weeks to issue the recall. You said yesterday that you were waiting for test results, but Metrc shows that all but a few of the tests were completed by 11/1. It's hard to understand why the MRA waited 15 days to issue a recall if this was truly a health and safety issue. We also discussed yesterday how four of the ten labs' results were consistent with Viridis' results, and yet it appears this recall is targeting Viridis only, and not those other labs. At a minimum, this should be a 3-lab recall since The Spot and Can-Lab both got the exact same result as Viridis (passed a sample with two consecutive negative tests after the sample was initially failed and not remediated). Also, we have been in contact

with A2LA, AOAC, and bioMerieux, who are all reviewing the data and have expressed serious concerns about your purported basis for this recall. I urge you again to let Viridis re-test these samples, or have an independent third party re-test them, or do an inter-lab test, or a proficiency test, or whatever test you want. Rushing into this recall on such flimsy, ill-advised rationale would be a colossal mistake that would cripple Viridis' business, wreak havoc on the entire industry, and raise serious questions about the MRA's integrity overall.

Finally, while we are sincerely interested in having further discussions and exploring any possible alternatives to this recall, we just want to reiterate that we feel like you've backed Viridis into a corner here and if you issue this recall, they will have no choice but to issue a press release to set the record straight and try to mitigate the damage from this ill-advised and completely illogical recall. We sincerely hope that won't be necessary, but we honestly don't feel like we have any other choice at this point unless the MRA drops this recall threat and starts working with us collaboratively to address the substance of your concerns. (It is well documented that we have been trying to have that dialogue with your staff since August to no avail; instead, it seems some have been spending all their time determined to find any potential reason to justify a recall).

Thank you,

Dave

David R. Russell

Attorney

Foster Swift Collins & Smith PC

313 S. Washington Square

Lansing, MI 48933

Phone: 517.371.8150

Fax: 517.367.7150

drussell@fosterswift.com

www.fosterswift.com

From: Mitchell, Desmond (LARA) [<mailto:MitchellD6@michigan.gov>]

Sent: Tuesday, November 16, 2021 4:57 PM

To: KBlair@honigman.com

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Russell, David; Hunt-Scully, Risa (AG)

Subject: FW: Follow up & Summary of test results & Draft Recall Bulletin

Importance: High

Kevin,

- I apologize for the delay. I've attached the recall bulletin for your review. Please provide any feedback or suggested revisions by 10 am on 11/17/2021. We'll review any proposed revisions and let you know if they will be adopted.
- Please see Claire's responses to your questions below.

If you have any questions, let me know. Thank you.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs

Telephone: (517) 243-9463
Email: mitchelld6@michigan.gov

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Tuesday, November 16, 2021 10:58 AM
To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>
Cc: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; drussell@fosterswift.com
Subject: RE: Follow up & Summary of test results

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Thank you for correcting that. I mean that sincerely. I appreciate you taking the time to triple check and correct that info. I just want to note, though, that the stakes here couldn't be any bigger. We're talking about health and safety, and we're here on the precipice of an enormous potential recall (that would cripple Viridis and raise serious questions about the integrity of the entire process) and one of the key data points that got us here wasn't just wrong in the initial chart, you also confirmed it again this morning via email. It wasn't until the third check that mistake was finally realized.

Also, I think it's critical to consider how many of the tests corroborate Viridis's samples. Just based on the "pass" results alone, that's 4 out of ten that are consistent with Viridis's results (and several of the other 6 were tested by competitors who have publicly talked about trying to put Viridis out of business, so how do you account for that obvious bias?).

For the retests in question, and for the sake of this conversation, we will exclude the test performed by Infinite because that sample should have been passing. This sample may be viewed as a control, in this case, and should rightly be excluded from any further data analysis.

With all this considered:

- Viridis performed 8 retests and passed 100% of them, failing 0% of the retests.
- Of the additional 8 retests performed by 4 separate facilities, 6 failed. That leaves us with a 25% passing rate and a 75% failure rate. This level of uncertainty is enough cause for concern.
- Regardless of competition, all scientists should be well versed in the ethical conduct of research. If they are not, they also are aware that all raw data and all data, in fact, is subject to scrutiny by the agency. I have no concerns about bias as the licensees were not told that this investigation had anything to do with Viridis. All labs were simply directed to pick up samples from the lab and from the grow. This is commonplace in all investigations that require retesting and does not single out the lab in particular as being part of the investigation.

Further, if any of the "fail" or "set to fail" cells had any test(s) pass, that's very important information to consider. If there was one pass and one fail, I understand that would be a fail under the rules. But if you're truly making data-driven decisions here, there shouldn't be any hesitation to share the data with us. If there were no negative tests associated with the "fail" or "set to fail" samples, why wouldn't you tell us that? And if there were, we'd like to know how many.

- I am not entirely sure of what you are asking in the case. Aside from the error that was corrected for sample number ending in -1014, all results are correct.
- There is no additional information to be provided here.
- If you are referring to an overall analysis of data, Viridis and Viridis North provide the 1st and 3rd most tests to the regulated market in Michigan.

- During this time of year, in particular, Aspergillus is incredibly common, with the average percentage of total flower packages tested resulting in an Aspergillus failure 9.43% of the time.
- The mean value on this data set is 7.42%.
- Despite the fact that Viridis and Viridis North perform the 1st and 3rd most tests in the state, they are only reporting aspergillus failures for 0.78% and 4.9% of those samples, respectively. Given that they fall well under both the median and average values for reporting, the data is considered anomalous and is being treated as such.

Kevin M. Blair

HONIGMAN LLP
 O 517.377.0716
kblair@honigman.com

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Tuesday, November 16, 2021 10:27 AM
To: Blair, Kevin M. <KBlair@honigman.com>; Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>
Cc: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; drussell@fosterswift.com
Subject: RE: Follow up & Summary of test results

[EXTERNAL EMAIL]

All,

Upon confirmation with COAs and data, I have updated a sample from The Spott to reflect a passing status for package:

1A4050300009155000001014

Please note that package:

1A4050300009155000001015

Is set as fail, and the overall retest result is set to fail.

Thank you,

Claire Patterson

Manager, Scientific & Legal Section
 Enforcement Division
 Marijuana Regulatory Agency

(517) 230-2097
PattersonC8@michigan.gov
www.michigan.gov/MRA

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From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Tuesday, November 16, 2021 10:00 AM
To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>
Cc: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; drussell@fosterswift.com
Subject: RE: Follow up & Summary of test results

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Claire –

Have you had a chance yet to check whether the first sample retested by The Spott (ending in 1014) was a pass or fail? Your chart shows a fail, but it appears in METRC as a pass.

Also, is there a difference on your chart between the cells that say “fail” vs “set to fail”? For example, does “fail” mean they had two positive tests whereas “set to fail” might mean they had one positive and one negative? If so, that is important information and context for us and Desmond to know (i.e., some of these samples may have tested negative 3 out of 4 times).

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Monday, November 15, 2021 1:38 PM
To: Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>; Blair, Kevin M. <KBlair@honigman.com>
Cc: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>
Subject: Follow up & Summary of test results

[EXTERNAL EMAIL]

Hi Greg,

As discussed on our call, I am attaching a summary of the test results for the tests in question.

All the best,

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

(517) 230-2097
PattersonC8@michigan.gov
www.michigan.gov/MRA

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Russell, David

From: Patrick Bird <consulting@pmbbiotek.com>
Sent: Wednesday, November 17, 2021 3:02 PM
To: Mitchell, Desmond (LARA); Blair, Kevin M.; Russell, David
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully, Risa (AG); Mark Fisk (mfisk@byrumfisk.com)
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

Good afternoon all.

Apologies for the late response. I've reviewed the email thread and had the opportunity to speak with all parties today (Claire, Desmond, Viridis Group) and have included a statement below summarizing the key points from these conversations. I also want to emphasize that I am a contract employee with AOAC, so I can't speak on their behalf.

1. AOAC INTERNATIONAL's role in the cannabis industry is to develop standards and guidance to allow alternative methods to be certified through one of its conformity assessment programs. The certification of the method demonstrates its fit for purpose for use in that industry if the method is performed as written in the validation guidelines. AOAC is not involved in laboratory assessment and/or accreditation.
2. Determining if a laboratory is performing a method correctly falls on the accreditation organization that issues the ISO 17025 certificate. If a method is certified during the accreditation it demonstrates that the laboratory is competent to run that method. The MRA's decision to recall these products due to the lack of traceability of the incubation logs indicates an issue with the accreditation process and not AOAC's certification. In this instance, the lab has demonstrated they can competently perform the method through their accreditation, although we all acknowledge there is a gap in the data collection process that fully supports this.
3. The additional testing of materials at other labs is not something that I believe supports a recall as there are many factors in play that may have lead to the different results (same batch but different test portions analyzed, time gaps in analysis from one lab to another, etc).

Again I want to reiterate that these statements are on my own accord but the first one is in alignment with AOAC's stated policies and procedures.

Best regards

Pat Bird

Patrick M. Bird

Principal Consultant of PMB BioTek Consulting
AOAC INTERNATIONAL Technical Consultant
330-730-8741
consulting@pmbbiotek.com



PMB BioTek Consulting

From: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>
Sent: Wednesday, November 17, 2021 11:48 AM
To: Blair, Kevin M. <KBlair@honigman.com>; Russell, David <DRussell@fosterswift.com>

EXHIBIT J



PUBLIC HEALTH AND SAFETY BULLETIN

November 17, 2021

Notification of Marijuana Product Recall

The Marijuana Regulatory Agency (MRA) has identified inaccurate and/or unreliable results of products tested by safety compliance facilities Viridis North, LLC and Viridis Laboratories, LLC.

In the interest of public health and safety, the MRA is issuing this health and safety advisory bulletin for **all** marijuana products tested by Viridis Laboratories, LLC (license numbers SC-000009 and AU-SC-000113) and Viridis North, LLC (license numbers SC-000014 and AU-SC-000103) **except** for inhalable marijuana concentrate products such as:

- Vape carts.
- Live resin.
- Distillate.
- Any other cannabis concentrate created through residual solvent extractions.

The marijuana products impacted have a test date between August 10, 2021 and November 16, 2021. All marijuana product labels are required to list the name and license number of the safety compliance facility that conducted the testing and date the product was tested.

Note: An MRA investigation is still on-going.

Consumers who have marijuana products in their possession that meet the recall criteria may return the products to the marijuana sales location where they were purchased for proper disposal. Consumers with weakened immune systems or lung disease are at the highest risk for health-related incidents such as aspergillosis, which can impact lung function, if these potentially harmful products are consumed.

Consumers who have experienced adverse reactions after using these products should report their symptoms and product use to their physician. Consumers are requested to report any adverse product reactions to the MRA via email: MRA-Enforcement@michigan.gov or via phone: 517-284-8599.

Marijuana sales locations that sold product covered by this bulletin must display this recall notice on the sales floor, visible to all customers, for 30 days from the date of this

This advisory bulletin does not constitute legal advice and is subject to change. Licensees are encouraged to seek legal counsel to ensure their operations comply with the Medical Marijuana Facilities Licensing Act and associated Administrative Rules.



PUBLIC HEALTH AND SAFETY BULLETIN

November 17, 2021

notice. Marijuana sales locations that receive adverse product reactions from consumers should report the adverse product reactions to the agency at MRA-Enforcement@michigan.gov and document these reports in METRC.

Licensees with products remaining in their inventory that meet the recall criteria have the following options:

- Destroy the product and provide proof of destruction: MRA-Compliance@michigan.gov.
- Have the product retested for the microbials compliance panel.
- Send the product back to the original licensee source so they can destroy or have the product retested as a larger batch.

Licensees that opt to have product sent back or retested will need to create new METRC packages with new METRC identification numbers prior to transferring or submitting the products for testing. Additional guidance can be provided to licensees who need assistance in creating these packages by reaching out to MRA-Compliance@michigan.gov.

Additional questions can be sent to the MRA's Operations Support Section: MRA-Compliance@michigan.gov.

EXHIBIT K

From: Patterson, Claire (LARA) [<mailto:PattersonC8@michigan.gov>]
Sent: Thursday, November 18, 2021 12:06 PM
To: Blair, Kevin M.; Kluytman, Julie (LARA); Mitchell, Desmond (LARA); MRA-scf
Cc: Todd Welch; Gregoire Michaud; Michele Glinn; Russell, David; Michael LaFramboise
Subject: RE: Tomorrow

The attached approval refers to Aspergillus testing only.

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

(517) 230-2097
PattersonC8@michigan.gov
www.michigan.gov/MRA



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From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Thursday, November 18, 2021 12:04 PM
To: Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; MRA-scf <MRA-scf@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Cc: Todd Welch <twelch@viridisgrp.com>; Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>; Russell, David <DRussell@fosterswift.com>; Michael LaFramboise <mlaframboise@viridisgrp.com>
Subject: FW: Tomorrow

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Following up on my last email, see highlighted language below as one example when Viridis was explicitly told they could resume testing. Viridis communicated that to customers based on the MRA's assurances and now it seems the MRA is contradicting what you said yesterday. Again, we need to get on the phone ASAP please.

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

From: MRA-scf <MRA-scf@michigan.gov>
Sent: Tuesday, November 16, 2021 5:51 PM
To: Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>
Cc: Blair, Kevin M. <KBlair@honigman.com>; Todd Welch <twelch@viridisgrp.com>;
drussell@fosterswift.com; Michael LaFramboise <mలాframboise@viridisgrp.com>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Rosenzweig, Noah (LARA) <RosenzweigN@michigan.gov>
Subject: RE: Tomorrow

[EXTERNAL EMAIL]

Greg,

Thank you and Michele for promptly sharing the incubator log for Viridis. As discussed earlier, Viridis is approved to move forward using the updated LOM-7.20 Gene-Up Aspergillus. A current method approval form for Viridis is attached. We will also cease placing Viridis Aspergillus tests on administrative hold. If outstanding questions remain, please let me know.

Patrice R. Fields, Ph.D.
Laboratory Scientist Specialist
Scientific & Legal Section, Enforcement Division
Marijuana Regulatory Agency
517-281-3640
FieldsP2@michigan.gov
www.michigan.gov/MRA



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From: Gregoire Michaud <gmichaud@viridisgrp.com>
Sent: Tuesday, November 16, 2021 4:12 PM
To: MRA-scf <MRA-scf@michigan.gov>
Cc: KBlair@honigman.com; Todd Welch <twelch@viridisgrp.com>; drussell@fosterswift.com; Michele Glinn <mglinn@viridisgrp.com>; Michael LaFramboise <miaframboise@viridisgrp.com>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Rosenzweig, Noah (LARA) <RosenzweigN@michigan.gov>
Subject: RE: Tomorrow

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See attached...thanks Patrice.

From: MRA-scf <MRA-scf@michigan.gov>
Sent: Tuesday, November 16, 2021 3:30 PM
To: Gregoire Michaud <gmichaud@viridisgrp.com>
Cc: KBlair@honigman.com; Todd Welch <twelch@viridisgrp.com>; drussell@fosterswift.com; Michele Glinn <mglinn@viridisgrp.com>; Michael LaFramboise <miaframboise@viridisgrp.com>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Rosenzweig, Noah (LARA) <RosenzweigN@michigan.gov>
Subject: RE: Tomorrow

Hi Greg,

Thank you for sharing these documents with us. After reviewing the incubator log, corrective action report, and the updated LOM-7.20 Gene-Up Aspergillus, Viridis North is approved to move forward using the SOP approved as of today to test for Aspergillus. We will also cease placing Viridis North Aspergillus tests on administrative hold. An updated method approval form for Viridis North is attached. While most of the same documentation also applies to Viridis, we are concerned that there is no current incubator log showing into and out of incubator times for Aspergillus test samples at that location. Due to this lack of records, we are withholding approval of the updated LOM-7.20 Gene-Up Aspergillus for Viridis and we will continue placing Viridis Aspergillus tests on administrative hold. The administrative holds for Viridis Aspergillus tests will cease once we have received records confirming that the approved SOP is being followed. If you have questions or concerns, please let me know.

Patrice R. Fields, Ph.D.

Laboratory Scientist Specialist
Scientific & Legal Section, Enforcement Division
Marijuana Regulatory Agency
517-281-3640
FieldsP2@michigan.gov
www.michigan.gov/MRA



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From: Gregoire Michaud <gmichaud@viridisgrp.com>

Sent: Monday, November 15, 2021 11:03 PM

To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>

Cc: Blair, Kevin M. <KBlair@honigman.com>; Todd Welch <twelch@viridisgrp.com>;

drussell@fosterswift.com; Michele Glinn <mglinn@viridisgrp.com>; Michael LaFramboise

<miaframboise@viridisgrp.com>

Subject: RE: Tomorrow

CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

Good evening Claire,

A little miscommunication at our end on who was going to get you these, sorry. Please find attached our corrective action and the two new logs that were put in place as a result of your audit. Bay City implemented the use of the incubator start/end times last Monday with Lansing starting today. Dr. Glinn was out of the lab all last week and the directive to start using it last Monday did not get relayed. We'll monitor it till the end of the month to ensure compliance is consistent at which point we will close out the corrective action. Also attached is our proposed revisions to the SOP that now reflect the use of the log (revisions highlighted in yellow).

Our apologies again for not getting these to you sooner.

Kind regards,

Greg

EXHIBIT L

STATE OF MICHIGAN
IN THE COURT OF CLAIMS

VIRIDIS LABORATORIES, LLC,
a Michigan limited liability company, and
VIRIDIS NORTH, LLC,
a Michigan limited liability company,

Case No. 21-_____-MB

Plaintiffs,

v.

MICHIGAN MARIJUANA REGULATORY
AGENCY, a Michigan state agency,
ANDREW BRISBO, Individually, JULIE
KLUYTMAN, Individually, DESMOND
MITCHELL, Individually, CLAIRE
PATTERSON, Individually.

Defendants.

David R. Russell (P68568)
Brandon M. H. Schumacher (P82930)
FOSTER, SWIFT, COLLINS & SMITH, P.C.
Counsel for Plaintiffs
313 S. Washington Square
Lansing, MI 48933
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Kevin M. Blair (P76927)
HONIGMAN, LLP
Co-Counsel for Plaintiffs
222 N. Washington Square, Suite 400
Lansing, MI 48933
(517) 377-0716
kblair@honigman.com

***EX PARTE ORDER TO SHOW CAUSE WHY
WRIT OF MANDAMUS SHOULD NOT BE GRANTED***

Plaintiffs Viridis Laboratories, LLC and Viridis North, LLC, filed an Ex Parte Motion for Mandamus on November 22, 2021 (the "Motion"). The Motion having been submitted to the Court as part of Plaintiffs' Verified Complaint pursuant MCR 3.305, and this Court having reviewed the Motion and Verified Complaint;

IT IS HEREBY ORDERED that Defendant Marijuana Regulatory Agency must show cause why the requested writ of mandamus compelling Defendant to immediately commence a contested case hearing before an administrative law judge on an expedited basis should not be issued, as provided for and permitted by MCR 3.305(C), at a hearing scheduled for _____, at _____.

Defendant must file an answer by _____.

Dated: _____, 2021

Hon. _____
Court of Claims Judge

36273:00001:5948388-1

EXHIBIT M



Method Approval Report

VALIDATION STATUS: (Approved / Not Approved)		METHOD NAME / SOP NUMBER: LOM 20 Detection of Aspergillus by Gene-Up/LOM 21 Detection of Salmonella and STEC by GENE-UP/LOM 22 TEMPO YM/CC	
FACILITY NAME Viridis Lansing		REVIEW DATE 08/05/2021	INSPECTION NUMBER SC-00009/AU-SC-000113
ADDRESS 2827 E. Saginaw St.		FACILITY TYPE Safety Compliance Facility/Marihuana Safety Compliance Facility	ASSIGNED AGENT LSS Rosenzweig
CITY, STATE ZIP CODE Lansing, MI 48912	FACILITY REPRESENTATIVE Michele Glinn		FACILITY PHONE 833-847-4347

INSPECTOR NOTES:

- ☐ STATUS (08/10/2021):
 - Approved for all analyses listed below on ALL MATRICES (flower, infused, concentrate):
 - Potency
 - Water Activity
 - Moisture Content
 - Chemical Residue
 - Metals
 - Foreign Matter
 - Microbials
 - Residual Solvent Analysis
 - Target Analytes
 - Terpenes

1. POTENCY

SOP: 7.1a Cannabinoid Analysis by UHPLC-DAD

Matrix: Flower

Instrument(s): Thermo Vanquish UHPLC System with VF-P10-A UHPLC pump and a Diode Array Detector (DAD) Lightpipe™ VH-D10, with a Restek sub-2 micron UHPLC column (Raptor ARC-18 LC Column 1.8 μ m 100 x 3.0 mm)

PT Results:

1/03/2020 – External Flower PT – non-matrix match (standard)



Method Approval Report

- Analytes: Delta9THC; CBD; CBDA; Delta9THCA; CBG; Delta8THC; THCV; CBDV; CBGA; CBC; CBDVA
- All results **ACCEPT**

3/12/2020 – External Hemp Oil PT – (standard)

- Analytes: Delta9THC; CBD; CBDA; Delta9THCA; CBG; Delta8THC; THCV; CBDV; CBGA; CBC; CBDVA
- All results **ACCEPT**

05/12/2020 – Gummy Matrix PT – (standard)

- Analytes: Delta9THC; CBD; CBDA; Delta9THCA; CBN; CBG; Delta8THC; THCV; CBDV; CBGA; CBC
- All results **ACCEPT**

Comments (4/16/2020):

- i. Method submitted and accepted on 01/24/2020 for analyses as written on Flower Matrix (ONLY)
- ii. Passing proficiency test submitted to the agency on 4/2/2020 Method Approved for analysis of concentrates.

Updates submitted: 7/08/2020

- *Potency approved on all matrices*

2. WATER ACTIVITY

SOP: 7.3 Moisture Content and Water Activity Analysis

Matrix: Flower

PT Results:

- PT – Flower - 01/03/2020 Water Activity – **ACCEPT**
- PT – Gummy - 03/11/2020 Water Activity - **ACCEPT**

Comments (4/10/2020):

- iii. Method submitted and accepted on 01/03/2020

Updates submitted:

3. MOISTURE CONTENT

SOP: 7.3 Moisture Content and Water Activity Analysis

Matrix: Flower

PT Results:

Acceptable PT is not required

Comments (4/16/2020):

- iv. Method submitted and accepted on 10/25/2019
- v. Not required on concentrates

Updates submitted:

4. CHEMICAL RESIDUE

SOP: 7.4a Chemical Residue / Pesticide Analysis by LC-MS/MS

Matrix: Flower

Instruments:

- 1. ThermoFisher Q Exactive Focus Hybrid Orbi-Trap Mass Spectrometer with Vanquish Binary UHPLC and Tracefinder software

August 21, 2020 – Added Instrument:

- 2. AB Sciex 6500 Triple Quadrupole LC-MS/MS with Exion liquid chromatograph and interchangeable ESI and APCI probes
- 3. OS-Q MS Data Analytics processing software

Note: Licensee has submitted appropriate validation and proficiency tests

PT Results:

2/21/2020 and 2/22/2020 Analyzed in solvent

- All analytes **ACCEPT**.

4/6/2020 Analyzed in hemp oil matrix – BLIND SAMPLE ANALYSIS

- All unknown target analytes **ACCEPT**.

7/01/2020 Analyzed in gummy matrix

- All unknown target analytes **ACCEPT**.

Comments (4/16/2020):

- vi. Method submitted and accepted on 01/24/2020 in Flower Matrix
- vii. Passing PT submitted as Blind Sample analysis, submitted to agency on 4/16/2020. Method approved for analysis of concentrates.

5. METALS

SOP: 7.2 Heavy Metal Analysis

Matrix: Flower; Concentrate

Instruments: ThermoFisher iCAP RQ ICP-MS with PrepFast injector port
prepFAST 4DX by Elemental Scientific
MARS6 Microwave-assisted acid digestion extraction system

PT Results:

1/03/2020 – External Flower PT – (hemp)

- Chromium; Nickel; Arsenic; Cadmium; Mercury; Lead
- All results: **ACCEPT**

3/12/2020 – External Hemp Oil PT – (hemp)

- Chromium; Nickel; Copper; Arsenic; Cadmium; Mercury; Lead
- All results: **ACCEPT**

3/24/2020 – Gummy Matrix PT

- Chromium; Arsenic; Cadmium; Mercury; Lead
- All results: **ACCEPT**

Comments:

- viii. **10/25/2019:** Method approved as written for flower matrix.
- ix. **01/24/2020:** Nickel and Copper added to previously approved method on flower matrix
- x. **04/16/2020:** Method approved for use on concentrate matrix
- xi. **04/28/2021** SMPR published 02/11/2021, the current method does not meet the SMPR requirements for the following analytes and will need to be updated: Lead, Mercury, and Cadmium before August 11, 2021.
- xii. **07/2/2021** Under Method Details Specimen Type is cannabis flower, but under Recovery it states: One cannabis flower sample in each run was analyzed in duplicate, with one aliquot used as the unspiked and one as the spiked sample. Gummies were purchased from a local grocery store. Please provide details on cannabis flower and associated metric tag numbers and results from gummy verification if seeking approval.
- xiii. **07/15/2021** Method now meets the SMPR requirements for Lead, Mercury, and Cadmium

Updates submitted:

Updates submitted:

07/15/2021 Provided details on cannabis flower and associated metric tag numbers and removed reference to gummies.

6. RESIDUAL SOLVENTS

SOP: 7.10 Residual Solvent Analysis

Matrix: Concentrate

PT Results:

4/14/2020 – External Hemp Oil PT – (hemp)

- All analytes present
- All results: **ACCEPT**

Comments (05/04/2020):

xiv. Method approved as written on concentrate matrix only.

SOP: 7.7 Terpenoid Analysis

Matrix: All

PT Results:

06/18/2020 – External Hemp Oil PT – (hemp)

- xv. a-Bisabolol, a-humulene, a-pinene, a-terpinolene, b-caryophyllene, myrcene, b-pinene, caryophyllene oxide, limonene, linalool.
- xvi. a-pinene, a-terpinolene, b-caryophyllene, myrcene, b-pinene, caryophyllene oxide, limonene: **ACCEPT**
- xvii. a-Bisabolol, a-humulene, linalool: **NOT ACCEPT**

Comments (09/01/2020): Terpene Analysis Added

- i. Method approved as written for the analysis of all terpenes listed below:
a-pinene, a-terpinolene, b-caryophyllene, myrcene, b-pinene, caryophyllene oxide, limonene: **ACCEPT**
- ii. The method may be approved for the following terpenes (below) when an acceptable PT is reported.
a-Bisabolol, a-humulene, linalool: **NOT ACCEPT**

04/28/2021 SMPR published 02/11/2021, the current method does not meet the SMPR requirements for the following analytes and will need to be updated: Ethanol, Heptane, Hexanes all isomers, 2,2-Dimethylbutane, 2,3-Dimethylbutane, 2-Methylpentane, 3-Methylpentane, Isopropyl alcohol, Methanol, Propane, Toluene and Total xylenes (ortho-, meta-, para-) before August 11, 2021.

07/23/2021 Method now meets the SMPR requirements for Ethanol, Heptane, Hexanes all isomers, 2,2-Dimethylbutane, 2,3-Dimethylbutane, 2-Methylpentane, 3-Methylpentane, Isopropyl alcohol, Methanol, Propane, Toluene and Total xylenes (ortho-, meta-, para-).

Updates submitted:

Updates submitted:

07/23/2021 Verification report for recovery of Ethanol, Heptane, Hexanes all isomers, 2,2-Dimethylbutane, 2,3-Dimethylbutane, 2-Methylpentane, 3-Methylpentane, Isopropyl alcohol, Methanol, Propane, Toluene and Total xylenes (ortho-, meta-, para-).

7. MICROBIAL ANALYSIS

SOP: 7.8 Plant-Micro DNA Extraction from Plant Material, LOM - 7.17 Total Yeast and Mold Plating and Count

LOM 20 Detection of Aspergillus by Gene-Up/LOM 21 Detection of Salmonella and STEC by GENE-UP/LOM 22 TEMPO YM/CC

Matrix: Flower

Instrumentation: Medicinal Genomics protocol as written and AriaMax

PT Results:

Flower – Hemp flower Matrix

APC (PCR- Quantitative) 10/21/2019 – ACCEPT

Total Coliform (PCR- Quantitative) 10/21/2019 – ACCEPT

E. coli (non-STECC) (PCR- Quantitative) 10/21/2019 – ACCEPT

Enterobacteriaceae (PCR- Quantitative) 10/21/2019 – ACCEPT

Yeast/Mold (PCR- Quantitative) 10/21/2019 – ACCEPT

Yeast and Mold (Plating) 2/01/2021 – ACCEPT

Concentrate – Hemp oil Matrix

Salmonella (PCR- Qualitative) 04/01/2020 – ACCEPT

Coliform (PCR): Externally Graded Not submitted, internal submitted– ACCEPT

Yeast and Mold (PCR): Externally Graded Not submitted, internal submitted– ACCEPT

STECC (PCR- Qualitative) 04/01/2020- ACCEPT

Total Mold (PCR- Qualitative): Externally Graded Not submitted, internal submitted– ACCEPT

Concentrate – Chocolate Matrix

Salmonella (PCR- Qualitative) 05/06/2020 – ACCEPT



Method Approval Report

STEC (PCR- Qualitative) 05/06/2020- ACCEPT

CMPT-028B Qualitative STEC in Hemp – Viridis Laboratories - NSI Lab Solutions/ FM-PTX1037

Analyst#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1	7034 E.coli STEC	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/19/21	David Chalmers
Sample 2	7034 E.coli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample 3	7034 E.coli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample 4	7034 E.coli STEC	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/19/21	David Chalmers
Sample 5	7034 E.coli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers

CMPT-029B Qualitative STEC in Edible – Viridis Laboratories - NSI Lab Solutions/ FM-PTX1037

Analyst#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1	7034 E.coli STEC	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/19/21	David Chalmers
Sample 2	7034 E.coli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample 3	7034 E.coli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample 4	7034 E.coli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample 5	7034 E.coli STEC	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/19/21	David Chalmers

CMPT-030B Qualitative STEC in Oil – Viridis Laboratories - NSI Lab Solutions/ FM-PTX1037

Analyst#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1	7034 E.coli STEC	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/19/21	David Chalmers
Sample 2	7034 E.coli STEC	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/19/21	David Chalmers
Sample 3	7034 E.coli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample 4	7034 E.coli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample 5	7034 E.coli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers



Method Approval Report

CMPT-025B Qualitative Salmonella In Hemp – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyte#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1	2057 Salmonella	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/14/21	David Chalmers
Sample 2	2057 Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers
Sample 3	2057 Salmonella	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/14/21	David Chalmers
Sample 4	2057 Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers
Sample 5	2057 Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers

CMPT-026B Qualitative Salmonella In Edible – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyte#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1	2057 Salmonella	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/14/21	David Chalmers
Sample 2	2057 Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers
Sample 3	2057 Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers
Sample 4	2057 Salmonella	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/14/21	David Chalmers
Sample 5	2057 Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers



Method Approval Report

CMPT-027B Qualitative Salmonella in Oil – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyst#	Analyst	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1								
2057	Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers
Sample 2								
2057	Salmonella	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/14/21	David Chalmers
Sample 3								
2057	Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers
Sample 4								
2057	Salmonella	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/14/21	David Chalmers
Sample 5								
2057	Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers

CMPT-031B Qualitative Aspergillus Molds in Hemp – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyst#	Analyst	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1								
6095	Total Mold	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 2								
6095	Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3								
6095	Total Mold	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 4								
6095	Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5								
6095	Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 1								
6096	A. fumigatus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2								
6096	A. fumigatus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3								
6096	A. fumigatus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4								
6096	A. fumigatus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5								
6096	A. fumigatus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers



Method Approval Report

Sample 1	6097 A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2	6097 A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3	6097 A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4	6097 A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5	6097 A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 1	6098 A. brasiliensis (Niger)	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 2	6098 A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3	6098 A. brasiliensis (Niger)	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 4	6098 A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5	6098 A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 1	6099 A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2	6099 A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3	6099 A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4	6099 A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5	6099 A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers

CMPT-032B Qualitative Aspergillus Molds in Edible – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyte#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1	6095 Total Mold	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 2	6095 Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3	6095 Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4	6095 Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5	6095 Total Mold	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 1	6096 A. fumigatus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2	6096 A. fumigatus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3	6096 A. fumigatus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4	6096 A. fumigatus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5	6096 A. fumigatus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 1	6097 A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2	6097 A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3	6097 A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4	6097 A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5	6097 A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers



Method Approval Report

Sample 1	6098	A. brasiliensis (Niger)	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 2	6098	A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3	6098	A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4	6098	A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5	6098	A. brasiliensis (Niger)	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 1	6099	A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2	6099	A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3	6099	A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4	6099	A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5	6099	A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers

CMPT-0338 Qualitative Aspergillus Molds In Oil – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyte#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1	6095 Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2	6095 Total Mold	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 3	6095 Total Mold	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 4	6095 Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5	6095 Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers



Method Approval Report

Sample 1	6096	A. fumigalis	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2	6096	A. fumigalis	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 3	6096	A. fumigalis	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 4	6096	A. fumigalis	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5	6096	A. fumigalis	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 1	6097	A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2	6097	A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3	6097	A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4	6097	A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5	6097	A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 1	6098	A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2	6098	A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3	6098	A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4	6098	A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5	6098	A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 1	6099	A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2	6099	A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3	6099	A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4	6099	A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5	6099	A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers

CMPT-040B Quantitative Yeast/Mold in Hemp – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyst#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Units	Acceptance Limits	Evaluation	Analysis Date	Analyst's Name
6057	Yeast/Mold	Tempo	MPN Tempo Biomeieux	210000	206000	cfu/g	82400 - 330000	ACCEPT.	06/29/21	David Chalmers

CMPT-059B Quantitative Yeast/Mold in Edible – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyst#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Units	Acceptance Limits	Evaluation	Analysis Date	Analyst's Name
6057	Yeast/Mold	Tempo	MPN Tempo Biomeieux	32000	35200	cfu/g	14100 - 56000	ACCEPT.	06/29/21	David Chalmers

CMPT-038B Quantitative Coliforms and E.coli in Edible – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyst#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Units	Acceptance Limits	Evaluation	Analysis Date	Analyst's Name
6053	Total Coliform	Biomeieux Tempo	MPN	340000	227605	cfu/g	94100 - 507900	ACCEPT.	06/29/21	David Chalmers

CMPT-037B Quantitative Coliforms and E.coli in Hemp – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyst#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Units	Acceptance Limits	Evaluation	Analysis Date	Analyst's Name
6053	Total Coliform	Biomeieux Tempo	MPN	480000	463000	cfu/g	185000 - 741000	ACCEPT.	06/29/21	David Chalmers

Comments (4/16/2020):



Method Approval Report

- iii. **1/03/2020:** Method approved as written. NOTE: Please submit upper level of quantitation for quantitative pcr methodology.
- iv. **1/24/2020:** ULOQ submitted in 01/21/2020 remediation response.
- v. **4/16/2020:** Method approved as written on concentrate matrix.
- vi. **04/28/2021:** The method for *Aspergillus*, *Salmonella*, and STEC does not meet the current SMPR's the agency published 02/11/2021, the facility will not be able to use this method after 08/11/2021.
- vii. **7/27/2021:** This review is only for the qualitative detection of *Aspergillus* spp. *Salmonella* spp. and STEC producing *Escherichia coli*. Raw data was not included with the validation report. Please include amplification curve and melt-curve raw data. Please include package insert for all assays referenced for MRA review. Please provide detailed information on thermocycler instrumentation, the manufacturer and model number. Humidity and temperature may interfere with the performance of the thermocycler instrument. Please include thermocycler manual to determine temperature range (°C) and relative humidity range (non-condensing). Please include environmental monitoring controls for the room where the testing will be conducted and an acceptable range for each on the log. Additionally, the bench log/worksheet should include information on the PCR plate well ID associated with test samples and controls. Please include the bench log/worksheet. Please include MRA acceptance criteria in SOPs.

This review is only for verification of total Coliform enumeration and total yeast and mold enumeration. Raw data was not included with the validation report. Please include raw data from either a .ted (TEMPO file) converted to .pdf, or .csv (Excel) file type. Please include package insert for all assays referenced for MRA review. Please provide detailed information on TEMPO instrumentation, the manufacturer and model number. If Humidity and temperature may interfere with the performance of the TEMPO instrument, please include TEMPO manual to determine temperature range (°C) and relative humidity range (non-condensing). Please include environmental monitoring controls for the room where the testing will be conducted and an acceptable range for each on the bench log/worksheet. Additionally, the log/worksheet should include information on how ID# associated with test samples and controls are logged. Please include the bench log sheet. Please include MRA acceptance criteria in SOPs.

- viii. **8/03/2021:** This review is only for the qualitative detection of *Aspergillus* spp. *Salmonella* spp. and STEC producing *Escherichia coli*. Please include amplification curve and melt-curve raw data for the *Aspergillus* spp. verification, data provided (beverage) was not from the matrices used in the verification study. Please include package insert for all assays referenced for MRA review, these should be available from the manufacturer's website directly. Humidity and temperature may interfere with the performance of the thermocycler instrument. Please include thermocycler manual to determine temperature range (°C) and relative humidity range (non-condensing).

This review is only for verification of total Coliform enumeration and total yeast and mold enumeration. Please provide detailed information on TEMPO instrumentation, specifically if Humidity and temperature may interfere with the performance of the TEMPO instrument, please include TEMPO Reading Station User's Manual (only quick start guides were provided) which includes General Characteristics with Environmental Considerations to determine operational temperature range (°C) and relative humidity range (non-condensing).

- ix. **8/10/2021:** The validation submitted for verification for the qualitative detection of *Aspergillus* spp., *Salmonella* spp. and STEC producing *Escherichia coli* method is thorough and satisfactorily addresses all requirements outlined in the Safety Compliance Facility Testing Guide.

The validation submitted for quantitative detection of total yeast and mold method is thorough and satisfactorily addresses all requirements outlined in the Safety Compliance Facility Testing Guide.

These methods are provisionally approved pending the results of the 09/13/2021-09/15/2021 ISO scope expansion.

Updates submitted:

Updates submitted:

8/03/2021: Included environmental monitoring controls for the room where the testing will be conducted and an acceptable range for each on the log. Included information on the PCR plate well ID associated with test samples and controls. Included the bench log/worksheet. Included MRA acceptance criteria in SOPs.

8/05/2021: Included amplification raw data for the *Aspergillus* spp. verification, package insert for all assays and thermocycler manual. Provided detailed information on TEMPO Reading Station

8. FOREIGN MATTER

SOP: 7.11 Foreign Matter Analysis and Photographic Imagine

Matrix: Flower

PT Results: 2/27/2020 – External Flower PT – (hemp)

- Visual analysis, filth/extraneous material \geq / \leq 5% - ACCEPT

Comments (4/16/2020):

- xx. **4/16/2020:** Method Approved: Concentrate and Flower Matrix

Updates submitted:

9. TARGET ANALYTES

SOP: LOM 7.14 Vitamin E Acetate Analysis by UHPLC-DAD

Matrix: Concentrate

PT Results:

- Vitamin E Acetate (05/04/2020)- ACCEPT

Comments:

07/08/2020: The MRA is notifying the laboratory that analyzing Vitamin E Acetate on UHPLC-DAD has the potential to result in false positive results due to matrix interference and misidentification of peaks. The occurrence of false negative results has not yet been demonstrated but is also hypothesized due to matrix interference. The laboratory is aware of potential interferences.

Updates submitted:

SOP: LOM 7.15 Vitamin E Acetate Analysis by LC-MS/MS

Matrix: Concentrate

PT Results:

- Vitamin E Acetate (10/23/2020)- ACCEPT

Comments:

10/30/2020: Laboratory submitted validation documents for addition of Vitamin E Acetate. Approved on 5/20/2020. The laboratory previously performed analysis of Vitamin E Acetate using an HPLC-DAD. The laboratory submitted an alternate protocol to detect Vitamin E Acetate using LC-MS/MS and will use this method going forward and use HPCL-DAD as a backup protocol.

ADDITIONAL ANALYSES – NOT REGULATED BY THE MRA

This section serves as acknowledgement that the laboratory has provided the MRA with the appropriate documentation and has notified the agency that they will be performing these analyses. The MRA does not require the following analyses.

1. Plant Gender Identification – Acknowledged.

All changes, updates, or additions to methodology must be submitted to the MRA for review and approval.

Assigned MRA Representative:

NAME: Claire T. Patterson, LSS Rosenzweig
ADDRESS: 2407 North Grand River Ave., Lansing, MI 48906
TELEPHONE: 517-230-2097, 517-243-4395
E-MAIL: RosenzweigN@michigan.gov

Rule 5(1) of the Sampling and Testing rule set (R. 420.305) A laboratory shall do all of the following: (a) Become fully accredited to the International Organization for Standardization (ISO), ISO/IEC 17025:2017 by an International Laboratory Accreditation Cooperation (ILAC) recognized accreditation body or by an entity approved by the agency within 1 year after the date the laboratory license is issued and agree to have the inspections and reports of the International Organization for Standardization made available to the agency.

If any of the methods on this approval report are not accredited by the expiration of the license, the approvals are rescinded in accordance with the rule above.

Complaint, Ex. J

Schumacher, Brandon

From: Patterson, Claire (LARA)
Sent: Friday, October 29, 2021 7:42 AM
To: Mitchell, Desmond (LARA)
Subject: RE: Inquiry to A2LA

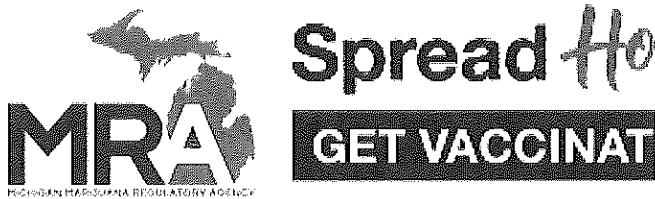
The answers are a little bit more avoidant than the response from the other two...but still supportive of the case. It seems as though they allow the labs to argue with them instead of just following guidelines as the other 3rd parties do.

I can forward to you if you'd like, I did include a summary of the most comprehensive response in the presentation for this morning.

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

(517) 230-2097
PattersonC8@michigan.gov
www.michigan.gov/MRA



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From: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>
Sent: Friday, October 29, 2021 7:29 AM
To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Subject: RE: Inquiry to A2LA

Thanks. Follow up with them again and let's see what happens.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463

Email: mitchelld6@michigan.gov

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Thursday, October 28, 2021 8:02 PM
To: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>
Subject: Inquiry to A2LA

Desmond,

Just so you are aware I was told earlier today by a representative at A2LA that the appropriate team member would reach out to me today.

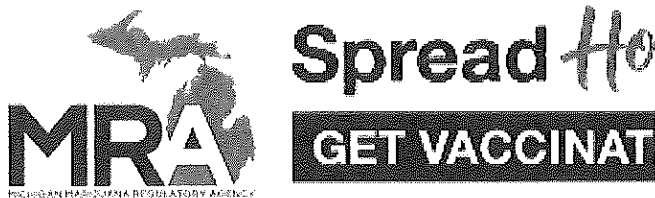
That individual has not yet responded to my questions.

Please note that this individual also performs on-site audits for labs in Michigan.

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

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Schumacher, Brandon

From: Chris Gunning <cgunning@a2la.org>
Sent: Friday, October 29, 2021 7:33 AM
To: Patterson, Claire (LARA)
Cc: Renee Delauter
Subject: RE: Questions regarding sample traceability

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Good morning Ms. Patterson,

Renee sent me your questions below as I perform training on the ISO/IEC 17025 standard for A2LA. Please see my answers to your questions below and feel free to reach out to me with any other questions.

Thanks,

Chris Gunning

A2LA | General Manager
Direct: 240 575 7481 | cgunning@A2LA.org
My Hours: 7:00 am – 3:30 pm (ET)

A2LA Office Hours: 8:00 am - 8:00 pm (ET)

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Thursday, October 28, 2021 8:53 AM
To: Renee Delauter <rdelauter@A2LA.org>; John Gumpper <jgumpper@chemval.com>
Subject: Questions regarding sample traceability

Good morning!

I hope this email finds you well. I have a few questions regarding traceability, and I just need some assistance confirming if my understanding is correct, and if it is not, I would welcome any correction and context you may be able to provide.

As I am reading through ISO 17025:2017 (and I am sure this was in 2012 as well), I see requirements that suggest that laboratories are required to keep track of temperatures on incubators and refrigerators that are in use for *any* portion of the data reporting process. This would include incubators that are used to incubate samples that are reported to customers and fridges that are used to, for instance, store standards and calibration material. Is this correct?

The area of the standard that discusses temperature monitoring would be found in section 6.3.3 which states:

The laboratory shall monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results.

So this does indeed require the lab to monitor and record quality critical temperatures. What it does not specify is how often the lab must record the temps. But they must prove that they are monitoring and recording them at some frequency while samples are being stored.

If a laboratory were using an incubator for the performance of a test, they would be expected to not only keep track of the temperature on a regular basis, but they would also be required to keep track of the in/out times of each batch of samples, and there should be a way to trace what samples are in that batch. Is this correct?

This particular requirement would be found in section 7.S.1 of the standard which states:

The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original.

The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results.

Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.

This requires the lab to record enough data to establish an audit trail but does not specify what must be recorded. I would certainly agree that they must be able to show what samples were in each batch. Times in and out of the incubator can be debatable depending on how the method is written. If an exact incubation time is written in the method, then it may be critical for the lab to show that they incubated for that exact time. But in the case of a range of time (i.e. 24 +/- 6 hours), the lab may be able to argue that time in and out are not as critical and therefore don't have to be recorded. That may also be supported by showing that their controls worked as intended. This clause is a bit tougher to enforce but we also expect to see reagents, samples, personnel and equipment recorded in the records.

If a laboratory noted a deviation in the temperature of an incubator or a refrigerator, they would be expected to note the deviation, identify any tests that may be impacted, and perform a full root cause analysis and subsequent CAPA, correct?

Yes and no. Clause 7.10 discusses nonconforming work and states:

7.10.1 The laboratory shall have a procedure that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The procedure shall ensure that:

- a) the responsibilities and authorities for the management of nonconforming work are defined;*
- b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;*
- c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;*

- d) a decision is taken on the acceptability of the nonconforming work;
- e) where necessary, the customer is notified and work is recalled;
- f) the responsibility for authorizing the resumption of work is defined.

7.10.2 The laboratory shall retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f).

7.10.3 Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory shall implement corrective action.

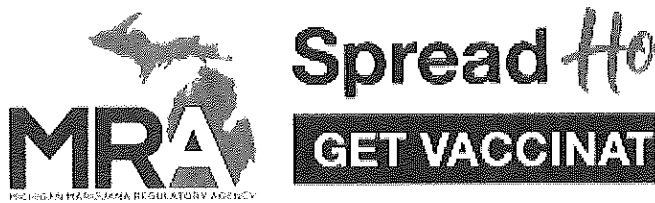
The lab must document the nonconforming work and investigate the impact of that nonconforming work. But 7.10.3 allows the lab to decide whether a full corrective action under clause 8.7 is necessary.

Thank you so much for your assistance, and I look forward to your response!

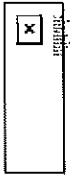
Claire Patterson

Manager, Scientific & Legal Section
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Schumacher, Brandon

From: Patrick Bird <consulting@pmbbiotek.com>
Sent: Friday, October 29, 2021 7:20 AM
To: Patterson, Claire (LARA)
Subject: RE: Question re: Incubation of microbial tests

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Good morning Claire,

It may be a simple question, although I'm not sure my answer will be simple 😊.

Depending on the target organism (s) an assay is looking to detect/quantify, the temperature that is validated not only can promote the target organisms growth, but also inhibit non-targets. In the food world, almost all Gram negative organisms (and lots of Gram positive and fungal organisms) will grow at 37C. These organisms are naturally present in any raw product, so for certain organisms (STEC) manufacturers will increase the temp to 42C as it doubles the time for reproduction in most of the non-targets, while still allowing STEC to double their growth every 20-30 min. Salmonella will still grow at this temperature as well, although not as quickly. Its why we have some methods that can claim an 8 or 10 h enrichment time for STEC but require 16-18 h for Salmonella, even from the same medium. Cannabis is really the only industry I've seen where a higher temp (37C) is used for fungal growth and its mainly due to Time to result, as well as trying to minimize the number of test portions a lab has to set up. Food labs will analyze fungal organisms at 20-28C because bacteria will grow much slower (plus there is usually antibacterial reagents added to the medium). So in short, temp is used two fold: promote the target and slow down non-targets.

Time requirements are a little more straightforward. Everyone wants to claim the fastest time to result they can. From a validation standpoint, we analyze the shortest time point in the study to make sure the method works correctly, and depending on the full temperature range, we may also require the later time point to be tested as well. Typically this means a range of greater than 6 h. So an 18-24 h test would only be validated at 18 h. A 16-24 h tests would be validated at 16 and 24 h, to make sure that non-competitive organisms don't out compete the targets and cause false negatives at the later range.

I hope this answers your question

Best regards

Pat

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Thursday, October 28, 2021 9:06 PM
To: Patrick Bird <consulting@pmbbiotek.com>
Subject: Question re: Incubation of microbial tests

Good evening Pat,

I have a quick question for you, and it may seem very remedial, but it is important.

When microbial test kits are PTM/OMA certified, the methods always include an incubation time and temperature range.

Obviously those times and temperatures are the environmental conditions that were specified by the manufacturer and were used in the validation of the test kits themselves.

Why are those parameters so important to the results of the test itself?

Thanks!

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

(517) 230-2097
PattersonC8@michigan.gov
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Archived: Wednesday, December 22, 2021 11:53:28 AM
From: MCINTYRE Maria
Sent: Sunday, November 14, 2021 1:19:31 PM
To: MRA-scf
Cc: MILLS John [Rosenzweig, Noah \(LARA\)](#) [Fields, Patrice \(LARA\)](#)
Subject: RE: Question about Gene-Up for Aspergillus
Importance: Normal
Sensitivity: None

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Hello Dr. Chirio,

My apologies for the oversight of this e-mail. Please advise if the contents of this message remain open topic. If so, I will address.

Kind regards,
Maria

Maria McIntyre
425-275-8013

From: MRA-scf <MRA-scf@michigan.gov>
Sent: Monday, October 25, 2021 4:27 AM
To: MCINTYRE Maria <maria.mcintyre@biomerieux.com>
Cc: MILLS John <John.MILLS@biomerieux.com>; Rosenzweig, Noah (LARA) <RosenzweigN@michigan.gov>; Fields, Patrice (LARA) <FieldsP2@michigan.gov>
Subject: RE: Question about Gene-Up for Aspergillus

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Hi Maria,

As you may know our job is to regulate the laboratories and to investigate complaints generated whether external or internal. The reason for asking if there are any obvious ways to game the system is that we have noticed a trend with one of our regulated facilities where if another testing laboratory using your platform or another AOAC PTM approved cannabis aspergillus platform fails a sample, this batch without any remediation is passing every time at one facility in particular. Flower batches are passing aspergillus without ever failing. In reviewing the information as a whole from 14 laboratories, this does not make logical sense. As you can imagine statistically this is impossible and they would need to be the luckiest laboratory or they are intentionally manipulating the testing.

From the investigation I have observed the following items and I am wondering if you or someone from your team can provide information on the effects of these items.

1. Incubator temperature below range listed in SOP.
2. Incubator temperature above range listed in SOP.
3. Refrigerator where reagents are stored above temperature listed in SOP.

4. Refrigerator where reagents are stored below temperature listed in SOP.

Any additional follow-up will assist us in our investigation. Our goal is to identify any sample manipulation and discipline the facility who is doing the manipulating to protect the health and safety of the consumers of Michigan. As you know aspergillus in cannabis users has been linked to Aspergillosis and additionally as a comorbidity with COVID infection so this is a public health threat. We have worked very hard to legitimize cannabis and laboratory testing and do not want anyone to take any steps backward or have anyone question the validity of the gene up platform. Without the MRA having the ability to test hypothesis, we rely heavily on our vendor validations for assistance. At this time we do not have a state laboratory where we could run samples in duplicate with conditions changed. We are not questioning your platform but we fear that we may have a bad actor who is intentionally trying to pass samples, and we need to figure out how they are doing it.

If you would prefer a phone call, I am available all day.

Best,

Dr. Allyson L. Chirio DHSc, MPH, BS(MT) (AMT)

Laboratory Scientist Specialist

Scientific & Legal Section, Enforcement Division

Marijuana Regulatory Agency

517-331-7512

ChirioA@michigan.gov

www.michigan.gov/MRA

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From: MCINTYRE Maria <maria.mcintyre@biomerieux.com>

Sent: Sunday, October 24, 2021 12:48 PM

To: MRA-scf <MRA-scf@michigan.gov>

Cc: MILLS John <John.MILLS@biomerieux.com>

Subject: RE: Question about Gene-Up for Aspergillus

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Hello Patrice,

The intention of bioMerieux is to create assays that are simple in workflow to reduce the error prone steps while maintaining scientific integrity. This is certainly the case for AspergillusPRO. There's likely value to have a conversation to expand and also understand if re-training is needed for a particular lab or labs. Please share a few schedule options that work for you and your team.

Kind regards,
Maria

Maria McIntyre
425-275-8013

From: MRA-scf <MRA-scf@michigan.gov>
Sent: Thursday, October 14, 2021 9:22 AM
To: MCINTYRE Maria <maria.mcintyre@biomerieux.com>
Cc: MILLS John <john.mills@biomerieux.com>
Subject: RE: Question about Gene-Up for Aspergillus

You don't often get email from mra-scf@michigan.gov. [Learn why this is important](#)

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Hi Maria,

I have one follow up question related to my original email. Are there any obvious ways (i.e. omitting steps, not following correct incubation times) that one could manipulate the Apergillus PRO system to produce negative results on a known positive sample?

Patrice R. Fields, Ph.D.

Laboratory Scientist Specialist
Scientific & Legal Section, Enforcement Division
Marijuana Regulatory Agency
517-281-3640
FieldsP2@michigan.gov
www.michigan.gov/MRA



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From: Fields, Patrice (LARA) <FieldsP2@michigan.gov>
Sent: Thursday, October 14, 2021 11:24 AM
To: MRA-scf <MRA-scf@michigan.gov>
Cc: Chirio, Allyson (LARA) <ChirioA@michigan.gov>; Rosenzweig, Noah (LARA) <RosenzweigN@michigan.gov>
Subject: FW: Question about Gene-Up for Aspergillus

FYI.....

From: MCINTYRE Maria <maria.mcintyre@biomerieux.com>
Sent: Thursday, October 14, 2021 11:19 AM

To: Fields, Patrice (LARA) <FieldsP2@michigan.gov>
Cc: MILLS John <John.MILLS@biomerieux.com>
Subject: RE: Question about Gene-Up for Aspergillus

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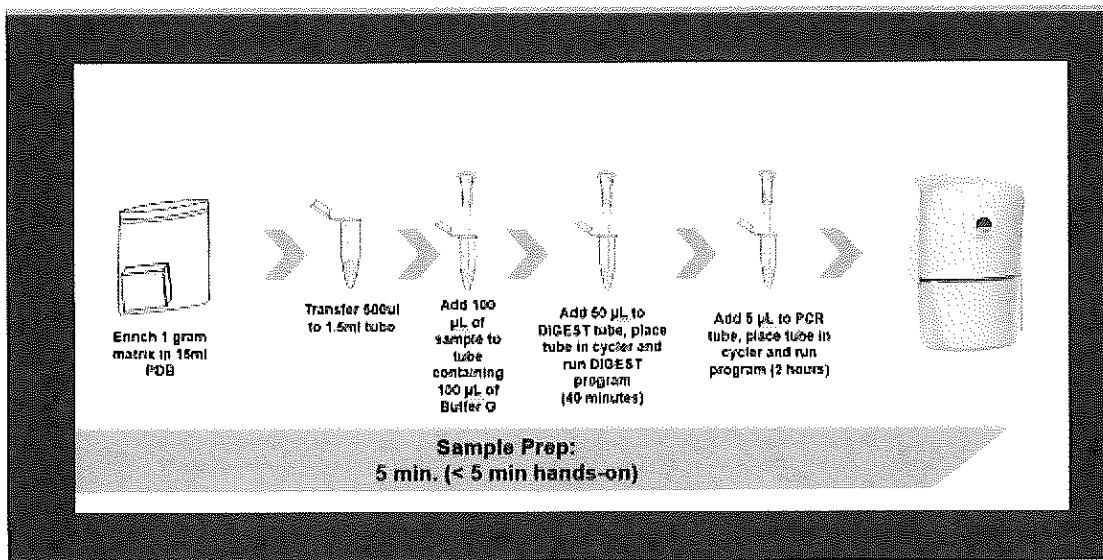
Hello Patrice,

Thanks for your message. For the AspergillusPRO assay there are 2 incubation options *regardless the matrix*. Both the 24h and the 48h are AOAC approved. The options provide labs to select a timeline that works best in their workflow and flexibility. In most cases labs are selecting one time and running that workflow in routine. There are differences in the workflow outside of time which are visually represented below. There are a few labs that opt to validate both to increase flexibility. Both workflows use the same kit and are AOAC approved.

If there's value to verbally walk through the assay, please advise.

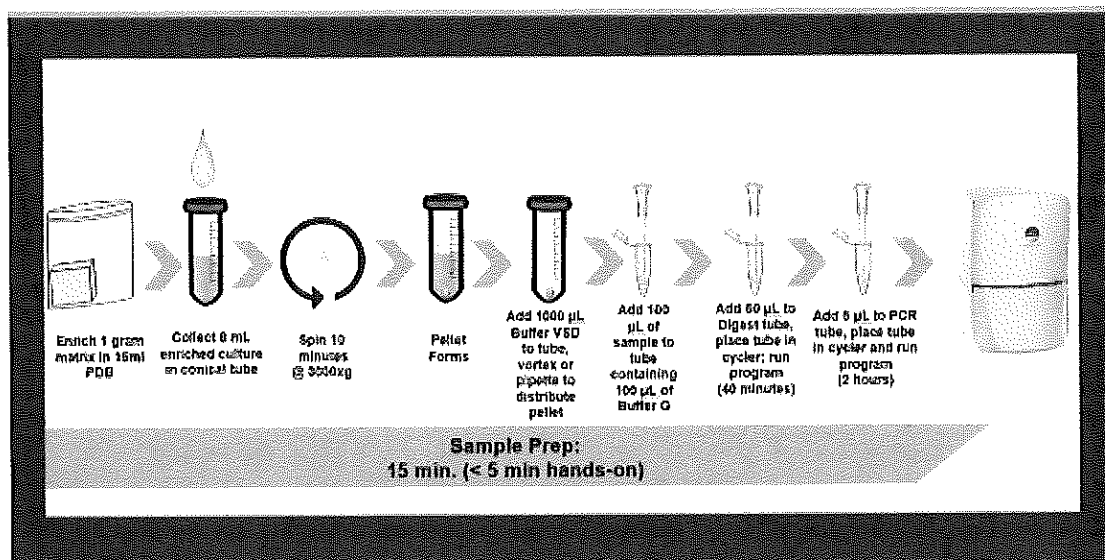
Workflow 48 Hour Protocol

INVISIBLE SENTINEL



Workflow 24 Hour Protocol

INVISIBLE SENTINEL



Kind regards,
Maria

Maria McIntyre
425-275-8013

From: Fields, Patrice (LARA) <FieldsP2@michigan.gov>
Sent: Thursday, October 14, 2021 7:27 AM
To: MCINTYRE Maria <maria.mcintyre@biomerieux.com>
Cc: MILLS John <john.mills@biomerieux.com>
Subject: Question about Gene-Up for Aspergillus

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Maria,

The MRA has received a question about the proper incubation time for cannabis products when using the Gene-Up for Aspergillus. Are there different suggested incubation times for flower versus other cannabis infused products? The PTM does not specify an incubation time to be used with cannabis-containing products, but the package insert that accompanies the platform seems to imply that the incubation time should be 48 hours for cannabis flower and 24 hours for other types of cannabis flower. Is that accurate or does that incubation time just need to be between 24 and 48 hours?

Patrice R. Fields, Ph.D.

Laboratory Scientist Specialist
Scientific & Legal Section, Enforcement Division
Marijuana Regulatory Agency
517-281-3640
FieldsP2@michigan.gov
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Complaint, Ex. K

Kluytman, Julie (LARA)

From: Kluytman, Julie (LARA)
Sent: Thursday, November 18, 2021 12:14 PM
To: Blair, Kevin M.; Todd Welch
Cc: MRA-scf; Patterson, Claire (LARA); Michael LaFramboise; Gregoire Michaud; Michele Glinn; Russell, David
Subject: RE: Viridis Re-testing

Kevin,

Please respond with your concerns in an email and I will address those concerns so there is no further misunderstanding.

We have repeatedly stated the microbial methods had nonconformances that also would result in inaccurate test results.

Are you stating that you intend to continue to test under the microbial conditions that resulted in the nonconformances or have those nonconformances been corrected?

If you have concerns regarding specific packages that were placed on hold, please provide those package numbers to me.

Thank you

Julie Kluytman, Enforcement Division Director
Marijuana Regulatory Agency
kluytmanj@michigan.gov

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Thursday, November 18, 2021 11:57 AM
To: Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Todd Welch <twelch@viridisgrp.com>
Cc: MRA-scf <MRA-scf@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Michael LaFramboise <miaframboise@viridisgrp.com>; Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>; Russell, David <DRussell@fosterswift.com>
Subject: RE: Viridis Re-testing

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Julie —

We need to get on the phone ASAP please. We were told multiple times that Viridis could resume testing, and the recall notice says the recall end date is 11/16, but we're seeing holds now on some material outside that timeframe.

Kevin

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

From: Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>
Sent: Thursday, November 18, 2021 11:22 AM
To: Todd Welch <twelch@viridisgrp.com>
Cc: MRA-scf <MRA-scf@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Blair, Kevin M. <KBlair@honigman.com>; Michael LaFramboise <mలాframboise@viridisgrp.com>; Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>
Subject: RE: Viridis Re-testing

[EXTERNAL EMAIL]

Hi Todd,
If you could document any additional questions you have I would be happy to respond to those questions and have a follow-up call to make sure the information contained within the response needs no additional clarification.

Thank you

From: Todd Welch <twelch@viridisgrp.com>
Sent: Thursday, November 18, 2021 10:33 AM
To: Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>
Cc: MRA-scf <MRA-scf@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Blair, Kevin M. <KBlair@honigman.com>; Michael LaFramboise <mలాframboise@viridisgrp.com>; Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>
Subject: RE: Viridis Re-testing

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Julie,

Thanks so much for your prompt response. We need to make absolutely certain that we are on the same page as again, that correspondence went out to all of our customers and Viridis relying on it to continue our business practice. Can you please get on a phone call with Michele, Greg, and I to lock this down as we cannot afford our ability to do business to be held up. Please let me know a good time to get on a quick call.

All the best,

Todd

From: Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>
Sent: Thursday, November 18, 2021 10:12 AM
To: Todd Welch <twelch@viridisgrp.com>
Cc: MRA-scf <MRA-scf@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Blair, Kevin M. <KBlair@honigman.com>; Michael LaFramboise <mలాframboise@viridisgrp.com>; Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>
Subject: Viridis Re-testing

Good Morning,

Your email was forwarded to me via the SCF email box, please note my email address is Kluytmanj@michigan.gov

The requirements for retesting the recalled product include the full microbial panel. As you are aware, there were also non-conformance audit findings related to current microbial Total Yeast and Mold testing standards. Have these issues been corrected and reported to the MRA?

Julie Kluytman, Enforcement Division Director
Marijuana Regulatory Agency
kluytmanj@michigan.gov

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Schumacher, Brandon

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Thursday, November 18, 2021 7:32 PM
To: Kluytman, Julie (LARA); Michele Glinn; Patterson, Claire (LARA); Gregoire Michaud; Todd Welch; Russell, David; Michael LaFramboise; Mitchell, Desmond (LARA)
Subject: RE: Audit follow up

Julie,

This is so incredibly frustrating. I really thought we had turned a corner. Everyone was professional on the Teams meeting and we had what we thought was a productive discussion. But somehow we fell for yet another bait and switch. I promise not to ever surreptitiously record our conversations without your consent, but maybe we should agree to record future conversations so there are no misunderstandings? Because I'm fairly certain no one ever said that Viridis has to complete everything on a list we hadn't even seen yet before resuming testing. You said that there were "more details" on Claire's list that needed to be addressed sometime soon, but the bolded agenda items were all that need to happen before testing resumes. Your response below doesn't even make sense. The whole purpose of that Teams meeting was to go over what needs to happen before testing resumes, and your agenda says "The MRA would expect the items in bold would be corrected prior to resuming testing in those specific areas of concern." So why not share the longer list ahead of the meeting? I had to specifically request it and then you rushed us to end the meeting before we realized that the highlighted list is longer and includes some items that cannot possibly be completed in less than a few days at least. Again, you are effectively shutting down Viridis but deliberately not following the established procedures to do so.

Specifically, I am asking about the items that are impossible to complete by tomorrow morning and whether Viridis is approved to begin testing by showing significant compliance with your arbitrary list. As a regulatory agency, clear communication is paramount and you and your colleagues have purposely continued to speak in vague terms. The MRA represented yesterday that after the logs were approved that Viridis could start testing again. We spent the entire day yesterday going back-and-forth on that single point with no mention of these items other than stating we would have a meeting to discuss on Monday. This morning, you moved the goal posts and immediately put holds on all Viridis items despite your representations. Your actions not only to continue to severely damage Viridis, but also its customers, which has created chaos in the industry. These actions do not further the public health and safety in any way.

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

From: Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>
Sent: Thursday, November 18, 2021 5:39 PM
To: Blair, Kevin M. <KBlair@honigman.com>; Michele Glinn <mglinn@viridisgrp.com>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Todd Welch <twelch@viridisgrp.com>; drussell@fosterswift.com; Michael LaFramboise <miaframboise@viridisgrp.com>; Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>
Subject: RE: Audit follow up

[EXTERNAL EMAIL]

Kevin,

The agenda states the bold items are a short summary of the corrective actions mentioned in the audit findings. I would not detail all the specific items needed from Claire's corrective action document in an agenda. This was explained in the meeting and the bold items correlate to the audit findings that were provided.

Julie Kluytman, Enforcement Division Director
Marijuana Regulatory Agency
kluytmanj@michigan.gov

From: Blair, Kevin M. <KBlair@honigman.com>

Sent: Thursday, November 18, 2021 5:12 PM

To: Michele Glinn <mglinn@viridisgrp.com>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Todd Welch <twelch@viridisgrp.com>; drussell@fosterswift.com; Michael LaFramboise <mLaframboise@viridisgrp.com>; Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>

Subject: RE: Audit follow up

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[Removed Kevin King]

Julie and Claire –

I believe you said and confirmed a few times on our Teams meeting just now that Viridis can resume microbial testing as soon as they complete the bolded items from Julie's agenda. Then the document Claire sent says everything highlighted has to be completed before testing resumes. That's exactly why I asked to see Claire's list before we logged off the meeting so there's no confusion about what needs to happen before testing resumes. One example is 4a that says Viridis must "[o]btain continuous, digital data monitoring devices for all incubators." Some of Viridis' incubators already have these, but some do not. We will order them tonight and pay for rush shipping, and provide proof of purchase. Can Viridis please resume testing once all the bolded items from Julie's agenda are completed as you repeatedly said on the Teams meeting, and we will provide proof that we're doing the rest of the highlighted list as fast as possible?

Here is a link to the devices we will order right now. Please confirm this is what you meant. Thank you.

https://www.avogadro-lab-supply.com/products/certified-digital-incubator-thermometer-50-to-70-c-cert-37%C2%BAc?variant=34426410959003¤cy=USD&utm_medium=product_sync&utm_source=google&utm_content=sag_organic&utm_campaign=sag_organic&gclid=Cj0KCQiAkNiMBhCxArisAIDDKNWDLSAbGAHqWEc1r1Sc-8Lk10UeQbmR320lubhJumkHkMx2dRCSigaAliKEALw_wcB

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716

Schumacher, Brandon

From: Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>
Sent: Thursday, November 18, 2021 8:39 PM
To: Blair, Kevin M.; Michele Glinn; Patterson, Claire (LARA); Gregoire Michaud; Todd Welch; Russell, David; Michael LaFramboise; Mitchell, Desmond (LARA)
Subject: RE: Audit follow up
Attachments: Viridis Agenda (002).docx

Kevin,

I am attaching the same agenda that was provided for the meeting, however I have "cut and pasted" directly from Claire's document where the items correlate to the agenda items as they were listed and I have highlighted the terms I used in the agenda so you can understand how I developed the agenda based on the more comprehensive document. To my knowledge, this is typically how agendas are created as they are intended to be lists of focal points for conversation and they don't typically include full conversations or documents.

I recall specifically addressing this in the meeting as Michele asked a question about the PCR and the TYM samples list because they were grouped together. I had placed them together for the agenda because I thought they were of the same topic but it was pointed out that there was some difference. Which is when we clarified again that Claire's document would provide more details and that I had placed these items together for the agenda.

Please let me know if there are any additional questions you have related to the requirements.

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Thursday, November 18, 2021 7:32 PM
To: Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Michele Glinn <mglinn@viridisgrp.com>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Todd Welch <twelch@viridisgrp.com>; drussell@fosterswift.com; Michael LaFramboise <mlaframboise@viridisgrp.com>; Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>
Subject: RE: Audit follow up

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Julie,

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Kevin M. Blair

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

From: Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>
Sent: Thursday, November 18, 2021 5:39 PM
To: Blair, Kevin M. <KBlair@honigman.com>; Michele Glinn <mglinn@viridisgrp.com>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Todd Welch <twelch@viridisgrp.com>; drussell@fosterswift.com; Michael LaFramboise <miaframboise@viridisgrp.com>; Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>
Subject: RE: Audit follow up

[EXTERNAL EMAIL]

Kevin,

The agenda states the bold items are a short summary of the corrective actions mentioned in the audit findings. I would not detail all the specific items needed from Claire's corrective action document in an agenda. This was explained in the meeting and the bold items correlate to the audit findings that were provided.

Julie Kluytman, Enforcement Division Director
Marijuana Regulatory Agency
kluytmanj@michigan.gov

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Thursday, November 18, 2021 5:12 PM
To: Michele Glinn <mglinn@viridisgrp.com>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Todd Welch <twelch@viridisgrp.com>; drussell@fosterswift.com; Michael LaFramboise <miaframboise@viridisgrp.com>; Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Subject: RE: Audit follow up

November 18, 2021

Agenda:

Meeting with Viridis and Viridis North

Purpose: Discuss Audit Finding Results and MRA Expectations

Audit Findings that require Corrective Action:

- Log this complaint
- Full audit by accrediting body and the MRA
- **The laboratory shall immediately institute a method for tracking samples in and out of ALL incubators.**
- **Temperature monitoring, revise temperature log, temperature log review**
- **Nonconforming TYM samples list and PCR run data provided to the agency**
- **Root cause analysis**
- Nonconforming foreign matter samples
- Label products appropriately
- Copy of all complaints sent to MRA

The items listed above are a short summary of the corrective actions mentioned in the audit findings. The MRA would expect the items in bold would be corrected prior to resuming testing in those specific areas of concern.

Schumacher, Brandon

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Thursday, November 18, 2021 5:12 PM
To: Michele Glinn; Patterson, Claire (LARA); Gregoire Michaud; Todd Welch; Russell, David; Michael LaFramboise; Mitchell, Desmond (LARA); Kluytman, Julie (LARA); Patterson, Claire (LARA)
Subject: RE: Audit follow up

[Removed Kevin King]

Julie and Claire –

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Kevin M. Blair

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

From: Michele Glinn <mglinn@viridisgrp.com>
Sent: Thursday, November 18, 2021 4:21 PM
To: Blair, Kevin M. <KBlair@honigman.com>
Subject: Fw: Audit follow up

[EXTERNAL EMAIL]

See below.

Best Regards,

Michele A. Glinn, PhD, F-ABFT
Chief Science Officer/Founder
E: mglinn@viridisgrp.com



From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Thursday, November 18, 2021 4:16 PM
To: Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>; Todd Welch <twelch@viridisgrp.com>; Kevin King <kevin@dragonflymichigan.com>; drussell@fosterswift.com <drussell@fosterswift.com>; Michael LaFramboise <miaframboise@viridisgrp.com>
Cc: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>
Subject: Audit follow up

Please see attached.

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

(517) 230-2097
PattersonC8@michigan.gov
www.michigan.gov/MRA



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Schumacher, Brandon

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Sent: Thursday, November 18, 2021 5:39 PM
To: Blair, Kevin M.; Michele Glinn; Patterson, Claire (LARA); Gregoire Michaud; Todd Welch; Russell, David; Michael LaFramboise; Mitchell, Desmond (LARA)
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Julie Kluytman, Enforcement Division Director
Marijuana Regulatory Agency
kluytmanj@michigan.gov

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Thursday, November 18, 2021 5:12 PM
To: Michele Glinn <mglinn@viridisgrp.com>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Todd Welch <twelch@viridisgrp.com>; drussell@fosterswift.com; Michael LaFramboise <mlaframboise@viridisgrp.com>; Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Subject: RE: Audit follow up

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[Removed Kevin King]

Julie and Claire –

I believe you said and confirmed a few times on our Teams meeting just now that Viridis can resume microbial testing as soon as they complete the bolded items from Julie's agenda. Then the document Claire sent says everything highlighted has to be completed before testing resumes. That's exactly why I asked to see Claire's list before we logged off the meeting so there's no confusion about what needs to happen before testing resumes. One example is 4a that says Viridis must "[o]btain continuous, digital data monitoring devices for all incubators." Some of Viridis' incubators already have these, but some do not. We will order them tonight and pay for rush shipping, and provide proof of purchase. Can Viridis please resume testing once all the bolded items from Julie's agenda are completed as you repeatedly said on the Teams meeting, and we will provide proof that we're doing the rest of the highlighted list as fast as possible?

Here is a link to the devices we will order right now. Please confirm this is what you meant. Thank you.

https://www.avogadro-lab-supply.com/products/certified-digital-incubator-thermometer-50-to-70-c-cert-37%C2%BAC?variant=34426410959003¤cy=USD&utm_medium=product_sync&utm_source=google&utm_content=sag_organic&utm_campaign=sag_organic&gclid=Cj0KCQIAkNiMBhCxARIsAIDDKNWDLSAbGAHqWEc1r1Sc-8Lk10UeQbmR320lubhJumkHkMx2dRCSigaAliKEALw_wcB

Schumacher, Brandon

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Thursday, November 18, 2021 7:32 PM
To: Kluytman, Julie (LARA); Michele Glinn; Patterson, Claire (LARA); Gregoire Michaud; Todd Welch; Russell, David; Michael LaFramboise; Mitchell, Desmond (LARA)
Subject: RE: Audit follow up

Julie,

This is so incredibly frustrating. I really thought we had turned a corner. Everyone was professional on the Teams meeting and we had what we thought was a productive discussion. But somehow we fell for yet another bait and switch. I promise not to ever surreptitiously record our conversations without your consent, but maybe we should agree to record future conversations so there are no misunderstandings? Because I'm fairly certain no one ever said that Viridis has to complete everything on a list we hadn't even seen yet before resuming testing. You said that there were "more details" on Claire's list that needed to be addressed sometime soon, but the bolded agenda items were all that need to happen before testing resumes. Your response below doesn't even make sense. The whole purpose of that Teams meeting was to go over what needs to happen before testing resumes, and your agenda says "The MRA would expect the items in bold would be corrected prior to resuming testing in those specific areas of concern." So why not share the longer list ahead of the meeting? I had to specifically request it and then you rushed us to end the meeting before we realized that the highlighted list is longer and includes some items that cannot possibly be completed in less than a few days at least. Again, you are effectively shutting down Viridis but deliberately not following the established procedures to do so.

Specifically, I am asking about the items that are impossible to complete by tomorrow morning and whether Viridis is approved to begin testing by showing significant compliance with your arbitrary list. As a regulatory agency, clear communication is paramount and you and your colleagues have purposely continued to speak in vague terms. The MRA represented yesterday that after the logs were approved that Viridis could start testing again. We spent the entire day yesterday going back-and-forth on that single point with no mention of these items other than stating we would have a meeting to discuss on Monday. This morning, you moved the goal posts and immediately put holds on all Viridis items despite your representations. Your actions not only to continue to severely damage Viridis, but also its customers, which has created chaos in the industry. These actions do not further the public health and safety in any way.

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

From: Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>
Sent: Thursday, November 18, 2021 5:39 PM
To: Blair, Kevin M. <KBlair@honigman.com>; Michele Glinn <mglinn@viridisgrp.com>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Todd Welch <twelch@viridisgrp.com>; drussell@fosterswift.com; Michael LaFramboise <mlaframboise@viridisgrp.com>; Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>
Subject: RE: Audit follow up

[EXTERNAL EMAIL]

Kevin,

The agenda states the bold items are a short summary of the corrective actions mentioned in the audit findings. I would not detail all the specific items needed from Claire's corrective action document in an agenda. This was explained in the meeting and the bold items correlate to the audit findings that were provided.

Julie Kluytman, Enforcement Division Director
Marijuana Regulatory Agency
kluytmanj@michigan.gov

From: Blair, Kevin M. <KBlair@honigman.com>

Sent: Thursday, November 18, 2021 5:12 PM

To: Michele Glinn <mglinn@viridisgrp.com>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Todd Welch <twelch@viridisgrp.com>; drussell@fosterswift.com; Michael LaFramboise <miaframboise@viridisgrp.com>; Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>

Subject: RE: Audit follow up

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[Removed Kevin King]

Julie and Claire --

I believe you said and confirmed a few times on our Teams meeting just now that Viridis can resume microbial testing as soon as they complete the bolded items from Julie's agenda. Then the document Claire sent says everything highlighted has to be completed before testing resumes. That's exactly why I asked to see Claire's list before we logged off the meeting so there's no confusion about what needs to happen before testing resumes. One example is 4a that says Viridis must "[o]btain continuous, digital data monitoring devices for all incubators." Some of Viridis' incubators already have these, but some do not. We will order them tonight and pay for rush shipping, and provide proof of purchase. Can Viridis please resume testing once all the bolded items from Julie's agenda are completed as you repeatedly said on the Teams meeting, and we will provide proof that we're doing the rest of the highlighted list as fast as possible?

Here is a link to the devices we will order right now. Please confirm this is what you meant. Thank you.

https://www.avogadro-lab-supply.com/products/certified-digital-incubator-thermometer-50-to-70-c-cert-37%C2%BAc?variant=34426410959003¤cy=USD&utm_medium=product_sync&utm_source=google&utm_content=sag_organic&utm_campaign=sag_organic&gclid=Cj0KCQiAkNiMBhCxArisAIDDKNWDLSAbGAHqWEc1r1Sc-8Lk10UeQbmR320lubhJumkHkMx2dRCSigaAlIKEALw_wcB

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716

From: Kevin King [<mailto:kevin@dragonflymichigan.com>]

Sent: Thursday, November 18, 2021 4:19 PM

To: Patterson, Claire (LARA)

Cc: Gregoire Michaud; Michele Glinn; Todd Welch; Russell, David; Michael LaFramboise; Mitchell, Desmond (LARA); Kluytman, Julie (LARA)

Subject: Re: Audit follow up

I believe this was sent to me in error. Is that confirmed?

Regards,

Kevin King

Director of Laboratory Operations

Dragonfly Kitchen II Inc | 26980 County Road 215 | Bangor, MI 49013

C: 708.846.4272

www.dragonflymichigan.com

Kevin@dragonflymichigan.com

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On Thu, Nov 18, 2021 at 4:16 PM Patterson, Claire (LARA) <PattersonC8@michigan.gov> wrote:

Please see attached.

Claire Patterson

Manager, Scientific & Legal Section

Enforcement Division

Marijuana Regulatory Agency

(517) 230-2097

PattersonC8@michigan.gov

www.michigan.gov/MRA



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Schumacher, Brandon

From: Schumacher, Brandon
Sent: Monday, November 22, 2021 1:29 PM
To: 'Mains, Douglas E.'; Blair, Kevin M.; Garrison, Emily E.; Russell, David
Subject: FW: Follow up & Summary of test results & Draft Recall Bulletin

Brandon M. H. Schumacher
Attorney
Foster Swift Collins & Smith PC
313 South Washington Square
Lansing, MI 48933-2193
Office Direct: 517.371.8255
Cell: 517.420.5741
Assistant: Sharla Clements: 517.371.8188
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bschumacher@fosterswift.com
www.fosterswift.com

FOSTER SWIFT

From: Russell, David
Sent: Wednesday, November 17, 2021 4:46 PM
To: Schumacher, Brandon
Subject: FW: Follow up & Summary of test results & Draft Recall Bulletin

David R. Russell
Attorney
Foster Swift Collins & Smith PC
313 S. Washington Square
Lansing, MI 48933
Phone: 517.371.8150
Fax: 517.367.7150
drussell@fosterswift.com
www.fosterswift.com

FOSTER SWIFT

From: MCINTYRE Maria [<mailto:maria.mcintyre@biomerieux.com>]
Sent: Wednesday, November 17, 2021 4:03 PM
To: Russell, David; 'Mitchell, Desmond (LARA)'; Blair, Kevin M.
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully, Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotek.com; MILLS John
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

Adding John Mills to the conversation.

1. Methods utilized have AOAC approval. This data collection usually includes robustness data that may or may not be a change in temperature. Please know, we are working to confirm if this data is available from

the work for AOAC. This may take time to capture as I am collaborating with John Mills- Scientific Affairs Manager and Dr. Ron Johnson- former AOAC President.

2. ISO 17025 accreditation impacts the discussion as ISO sets the benchmark for the quality standards within accredited laboratories. If a recall is generated under these circumstances it's a reflection of a gap in ISO accreditation and does not relate to AOAC or the method itself. The lab has completed training on the method reflected in the training certificates and demonstrated via the ISO 17025 accreditation process.
3. When there is uncertainty in results either retesting or confirmation testing generally holds greater value than a multi-lab study. In such a study, there are many variable in the equation leading to variability.
4. The iso files have been reviewed and the assay appears to be running properly. The files have been transferred to the R&D team who created this assay for a 2nd opinion and to determine if other areas require addressing.

Kind regards,
Maria

Maria McIntyre
425-275-8013

From: Russell, David <DRussell@fosterswift.com>
Sent: Wednesday, November 17, 2021 11:59 AM
To: 'Mitchell, Desmond (LARA)' <MitchellD6@michigan.gov>; Blair, Kevin M. <KBlair@honigman.com>
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com; MCINTYRE Maria <maria.mcintyre@biomerieux.com>
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

You don't often get email from drussell@fosterswift.com. [Learn why this is important](#)

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Desmond – I would ask for just a few more minutes. We have spoken with both Ms. McIntyre and Mr. Bird and they are working on sending those now. Thanks.

David R. Russell
Attorney
Foster Swift Collins & Smith PC
313 S. Washington Square
Lansing, MI 48933
Phone: 517.371.8150
Fax: 517.367.7150
drussell@fosterswift.com
www.fosterswift.com

FOSTER SWIFT

From: Mitchell, Desmond (LARA) [<mailto:MitchellD6@michigan.gov>]
Sent: Wednesday, November 17, 2021 1:48 PM
To: Blair, Kevin M.; Russell, David
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully, Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotek.com
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

Kevin,

I can't wait until tomorrow. I'll give you until 3 pm. Also, you're aware that the absence of the logs is only part of the issue.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchelld6@michigan.gov

From: Blair, Kevin M. <KBlair@honigman.com>

Sent: Wednesday, November 17, 2021 1:39 PM

To: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Russell, David <DRussell@fosterswift.com>

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com

Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Desmond –

You said repeatedly yesterday that the absence of logs alone would not justify a recall. You pointed to the test results as the primary basis for warranting a recall. But recall that there are no test results at all related to Viridis North's results. At a minimum, Viridis North should be carved out of this recall. They are a separate licensee, with different ownership, and there is no reason they should get swept into this crippling recall just because their name also includes the word "Viridis."

Also, we are doing all we can to reconnect with Mr. Bird and Ms. McIntyre to get statements from them. They are tied up in other meetings and we haven't been able to reach them, but again, Mr. Bird has been copied on all these emails and we're confident that we have not misrepresented his views. We are asking that you give us until 8:30 tomorrow to get those statements. The stakes here couldn't be any higher, and we urge you not to rush forward with this simply because these folks weren't instantaneously available to drop everything and write statements.

Kevin

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

From: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>
Sent: Wednesday, November 17, 2021 12:52 PM
To: Russell, David <DRussell@fosterswift.com>; Blair, Kevin M. <KBlair@honigman.com>
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

[EXTERNAL EMAIL]

Have them submit those exact statements to me in writing and I'll consider discussing it further.

Also, that's not evidence my staff leaked it.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchellD6@michigan.gov

From: Russell, David <DRussell@fosterswift.com>
Sent: Wednesday, November 17, 2021 12:45 PM
To: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Blair, Kevin M. <KBlair@honigman.com>
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Desmond,

I know Kevin is driving, and this is extremely important, so I want to respond immediately. We have Mr. Bird, copied on this e-mail, and Marie McIntyre from bioMeriux that support our position that this recall is not appropriate. We are not sure how there could be any other explanation than retaliation when you have Mr. Bird stating this recall is inappropriate and Ms. McIntyre from the manufacturer of the platform stating that these retests do not support your position and yet the MRA insists on moving forward. We would ask to at least have the opportunity to get everyone on a call to discuss. The stakes are way too big here to risk a miscommunication that you suggest in your e-mail below. Please remember that Mr. Bird has been copied on all of these e-mails. This will destroy Viridis.

We certainly have evidence that there are leaks. There are people that knew the August 10th start date from your recall notice, which is not public information, early this morning.

Please let me know if we can set up a call.

Dave

David R. Russell
Attorney
Foster Swift Collins & Smith PC
313 S. Washington Square
Lansing, MI 48933
Phone: 517.371.8150
Fax: 517.367.7150
drussell@fosterswift.com
www.fosterswift.com

FOSTER SWIFT

From: Mitchell, Desmond (LARA) [<mailto:MitchellD6@michigan.gov>]
Sent: Wednesday, November 17, 2021 12:24 PM
To: Blair, Kevin M.
Cc: Russell, David; gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully, Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotek.com
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

Kevin,

As I've repeatedly stated, no one at the MRA is angry with Viridis. We're just following through with our regulatory responsibilities.

As far as your allegation about staff leaking information regarding the recall, do you have any evidence to support it?

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchelld6@michigan.gov

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Wednesday, November 17, 2021 12:17 PM
To: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>
Cc: Russell, David <DRussell@fosterswift.com>; gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com
Subject: Re: Follow up & Summary of test results & Draft Recall Bulletin

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I'm begging you to please get on teams or phone to discuss and try and find a way for cooler heads to prevail. We truly believe this would be a huge mistake. It's one of the biggest recalls ever in the country based on the flimsiest of reasons.

Also, we've heard from countless people in the industry this morning that already know precise details about this recall. They didn't get that info from us so you have at least one staff member so happy about this recall that they're leaking it to the industry beforehand. That alone should give you pause and reconsider the clear biases of some of those who are trying to convince you that this is a safety issue.

Sent from my iPhone

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

On Nov 17, 2021, at 11:46 AM, Mitchell, Desmond (LARA) <MitchellD6@michigan.gov> wrote:

[EXTERNAL EMAIL]

Good Morning Dave,

Thank you for the feedback. Please note the following:

1. Claire also spoke to Mr. Bird and I don't believe your statements are a full and accurate representation of his point of view.
2. I'm not comfortable with your proposed revisions. I believe our initial draft provides a more accurate representation of the situation to the public and consumers. As a result, the attached bulletin is the one that will be issued today.
3. The investigation is still ongoing. As part of that investigation, we'll determine if the recall should be expanded as you've indicated. If it does, we'll expand the recall. However, as Kevin has pointed out before this is a public health and safety issue and we need to act on this as soon as possible. I believe there is currently sufficient evidence for us to proceed.
4. The MRA is also open to and believes it is necessary to continue to have discussions after the recall is issued and hopefully prevent something like this from happening in the future.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchellD6@michigan.gov

From: Russell, David <DRussell@fosterswift.com>
Sent: Wednesday, November 17, 2021 9:55 AM
To: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; KBlair@honigman.com
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA)

<KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; 'consulting@pmbbiotech.com' <consulting@pmbbiotech.com>
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Good morning, Desmond.

In conversations yesterday and today with Pat Bird, a consultant with the AOAC, Mr. Bird has confirmed to Viridis that not having sample incubation times tracked is not a divergence from the approved AOAC method. Further, Mr. Bird agreed that use of the 10 sample tests sent to five different laboratories is not an appropriate method to confirm Viridis' testing for *Aspergillus* and an improper reason to issue a recall. Additionally, Viridis has had conversations with Marie McIntyre from bioMeriux and she too has opined that the MRA's use of the 10 sample tests is not a proper way to confirm Viridis' retests. I have copied Pat Bird on this e-mail, so he can confirm our conversation if necessary or answer any questions that you may have. It is my understanding that Mr. Bird called Ms. Patterson this morning to discuss this matter and he has indicated a willingness to speak to you as well.

Notwithstanding the fact that Viridis strongly disagrees that any recall is appropriate, at your request, I'm attaching clean and redline versions of your proposed recall bulletin with our proposed changes. While we strongly disagree with your analysis and decision to issue this recall, we respectfully submit that if health and safety is truly your main concern, you can accomplish the exact same result without all the alarmist and defamatory language you included in the first draft. We also truly don't understand why the scope of this recall includes all products (except inhalable concentrates). The proposed recall would encompass approximately 64,489 lbs. of flower (not counting trim, concentrates, etc.) over this period and using the average retail price per lbs. would total \$229,645,329.

All of our discussions thus far have focused on *aspergillus*, and yet this recall is essentially saying you don't trust any test results at all from Viridis (even products that were tested only for terpenes, potency, or other tests that have nothing to do with *aspergillus* tests). Therefore, any recall should focus solely on *aspergillus* results. As we discussed yesterday, 8/10 has no logical connection to the *aspergillus* test issues, and if the absence of logs alone justifies a recall, this recall should cover everything Viridis has tested for *aspergillus* since 2019. If, on the other hand, the recall is based on the competitors' test results, then the earliest collection date is 9/13.

Second, we respectfully urge you again to reconsider. This is a truly unprecedented and illogical recall. When Iron Laboratories was caught red handed falsifying records and deceiving consumers about the presence of dangerous pesticides, the MRA said it "has not been made aware of any adverse product reactions in conjunction with product tested by Iron Laboratories and is not recalling any marijuana product at this time." In contrast here, Viridis has been performing these tests for two years with the MRA's full knowledge, the MRA has observed these tests countless times and never said a word about not having incubator timing logs until 10/26/21. As soon as the MRA raised this issue, Viridis agreed to begin keeping these logs. And even after the MRA first raised this on 10/26, you waited another 3 weeks to issue the recall. You said yesterday that you were waiting for test results, but Metro shows that all but a few of the tests were completed by 11/1. It's hard to understand why the MRA waited 15 days to issue a recall if this was truly a health and safety issue. We also discussed yesterday

how four of the ten labs' results were consistent with Viridis' results, and yet it appears this recall is targeting Viridis only, and not those other labs. At a minimum, this should be a 3-lab recall since The Spot and Can-Lab both got the exact same result as Viridis (passed a sample with two consecutive negative tests after the sample was initially failed and not remediated). Also, we have been in contact with A2LA, AOAC, and bioMerieux, who are all reviewing the data and have expressed serious concerns about your purported basis for this recall. I urge you again to let Viridis re-test these samples, or have an independent third party re-test them, or do an inter-lab test, or a proficiency test, or whatever test you want. Rushing into this recall on such flimsy, ill-advised rationale would be a colossal mistake that would cripple Viridis' business, wreak havoc on the entire industry, and raise serious questions about the MRA's integrity overall.

Finally, while we are sincerely interested in having further discussions and exploring any possible alternatives to this recall, we just want to reiterate that we feel like you've backed Viridis into a corner here and if you issue this recall, they will have no choice but to issue a press release to set the record straight and try to mitigate the damage from this ill-advised and completely illogical recall. We sincerely hope that won't be necessary, but we honestly don't feel like we have any other choice at this point unless the MRA drops this recall threat and starts working with us collaboratively to address the substance of your concerns. (It is well documented that we have been trying to have that dialogue with your staff since August to no avail; instead, it seems some have been spending all their time determined to find any potential reason to justify a recall).

Thank you,

Dave

David R. Russell
Attorney
Foster Swift Collins & Smith PC
313 S. Washington Square
Lansing, MI 48933
Phone: 517.371.8150
Fax: 517.367.7150
drussell@fosterswift.com
www.fosterswift.com

From: Mitchell, Desmond (LARA) [<mailto:MitchellD6@michigan.gov>]
Sent: Tuesday, November 16, 2021 4:57 PM
To: KBlair@honigman.com
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Russell, David; Hunt-Scully, Risa (AG)
Subject: FW: Follow up & Summary of test results & Draft Recall Bulletin
Importance: High

Kevin,

- I apologize for the delay. I've attached the recall bulletin for your review. Please provide any feedback or suggested revisions by 10 am on 11/17/2021. We'll review any proposed revisions and let you know if they will be adopted.
- Please see Claire's responses to your questions below.

If you have any questions, let me know. Thank you.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchelld6@michigan.gov

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Tuesday, November 16, 2021 10:58 AM
To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>
Cc: Mitchell, Desmond (LARA) <Mitchelld6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; drussell@fosterswift.com
Subject: RE: Follow up & Summary of test results

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Thank you for correcting that. I mean that sincerely. I appreciate you taking the time to triple check and correct that info. I just want to note, though, that the stakes here couldn't be any bigger. We're talking about health and safety, and we're here on the precipice of an enormous potential recall (that would cripple Viridis and raise serious questions about the integrity of the entire process) and one of the key data points that got us here wasn't just wrong in the initial chart, you also confirmed it again this morning via email. It wasn't until the third check that mistake was finally realized.

Also, I think it's critical to consider how many of the tests corroborate Viridis's samples. Just based on the "pass" results alone, that's 4 out of ten that are consistent with Viridis's results (and several of the other 6 were tested by competitors who have publicly talked about trying to put Viridis out of business, so how do you account for that obvious bias?).

For the retests in question, and for the sake of this conversation, we will exclude the test performed by Infinite because that sample should have been passing. This sample may be viewed as a control, in this case, and should rightly be excluded from any further data analysis.

With all this considered:

- Viridis performed 8 retests and passed 100% of them, failing 0% of the retests.
- Of the additional 8 retests performed by 4 separate facilities, 6 failed. That leaves us with a 25% passing rate and a 75% failure rate. This level of uncertainty is enough cause for concern.
- Regardless of competition, all scientists should be well versed in the ethical conduct of research. If they are not, they also are aware that all raw data and all data, in fact, is subject to scrutiny by the agency. I have no concerns about bias as the licensees were not told that this investigation had anything to do with Viridis. All labs were simply directed to pick up samples from the lab and from the grow. This is commonplace in all investigations that require retesting and does not single out the lab in particular as being part of the investigation.

Further, if any of the "fail" or "set to fail" cells had any test(s) pass, that's very important information to consider. If there was one pass and one fail, I understand that would be a fail under the rules. But if you're truly making data-driven decisions here, there shouldn't be any hesitation to share the data with us. If there were no negative tests associated with the "fail" or "set to fail" samples, why wouldn't you tell us that? And if there were, we'd like to know how many.

- I am not entirely sure of what you are asking in the case. Aside from the error that was corrected for sample number ending in -1014, all results are correct.

- There is no additional information to be provided here.
- If you are referring to an overall analysis of data, Viridis and Viridis North provide the 1st and 3rd most tests to the regulated market in Michigan.
- During this time of year, in particular, Aspergillus is incredibly common, with the average percentage of total flower packages tested resulting in an Aspergillus failure 9.43% of the time.
- The mean value on this data set is 7.42%.
- Despite the fact that Viridis and Viridis North perform the 1st and 3rd most tests in the state, they are only reporting aspergillus failures for 0.78% and 4.9% of those samples, respectively. Given that they fall well under both the median and average values for reporting, the data is considered anomalous and is being treated as such.

Kevin M. Blair

HONIGMAN LLP
 O 517.377.0716
kblair@honigman.com

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Tuesday, November 16, 2021 10:27 AM
To: Blair, Kevin M. <KBlair@honigman.com>; Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>
Cc: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; drussell@fosterswift.com
Subject: RE: Follow up & Summary of test results

[EXTERNAL EMAIL]

All,

Upon confirmation with COAs and data, I have updated a sample from The Spott to reflect a passing status for package:

1A4050300009155000001014

Please note that package:

1A4050300009155000001015

Is set as fail, and the overall retest result is set to fail.

Thank you,

Claire Patterson

Manager, Scientific & Legal Section
 Enforcement Division
 Marijuana Regulatory Agency

(517) 230-2097

PattersonC8@michigan.gov
www.michigan.gov/MRA

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From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Tuesday, November 16, 2021 10:00 AM
To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>
Cc: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; drussell@fosterswift.com
Subject: RE: Follow up & Summary of test results

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Claire –

Have you had a chance yet to check whether the first sample retested by The Spott (ending in 1014) was a pass or fail? Your chart shows a fail, but it appears in METRC as a pass.

Also, is there a difference on your chart between the cells that say “fail” vs “set to fail”? For example, does “fail” mean they had two positive tests whereas “set to fail” might mean they had one positive and one negative? If so, that is important information and context for us and Desmond to know (i.e., some of these samples may have tested negative 3 out of 4 times).

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Monday, November 15, 2021 1:38 PM
To: Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>; Blair, Kevin M. <KBlair@honigman.com>
Cc: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>
Subject: Follow up & Summary of test results

[EXTERNAL EMAIL]

Hi Greg,

As discussed on our call, I am attaching a summary of the test results for the tests in question.

All the best,

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

(517) 230-2097
PattersonC8@michigan.gov
www.michigan.gov/MRA

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Schumacher, Brandon

From: Schumacher, Brandon
Sent: Monday, November 22, 2021 1:29 PM
To: 'Mains, Douglas E.'; Garrison, Emily E.; Blair, Kevin M.; Russell, David
Subject: FW: Follow up & Summary of test results & Draft Recall Bulletin

Brandon M. H. Schumacher

Attorney
Foster Swift Collins & Smith PC
313 South Washington Square
Lansing, MI 48933-2193
Office Direct: 517.371.8255
Cell: 517.420.5741
Assistant: Sharla Clements: 517.371.8188
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bschumacher@fosterswift.com
www.fosterswift.com

FOSTER SWIFT

From: Russell, David
Sent: Wednesday, November 17, 2021 4:46 PM
To: Schumacher, Brandon
Subject: FW: Follow up & Summary of test results & Draft Recall Bulletin

David R. Russell

Attorney
Foster Swift Collins & Smith PC
313 S. Washington Square
Lansing, MI 48933
Phone: 517.371.8150
Fax: 517.367.7150
drussell@fosterswift.com
www.fosterswift.com

FOSTER SWIFT

From: Russell, David
Sent: Wednesday, November 17, 2021 4:43 PM
To: 'Mitchell, Desmond (LARA)'; MCINTYRE Maria; Blair, Kevin M.
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully, Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotek.com; MILLS John
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

Once you have issued the recall the irreparable damage is done to this business. You have two subject matter experts opining that the recall is not appropriate based on your "tests".

David R. Russell

Attorney
Foster Swift Collins & Smith PC
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Lansing, MI 48933
Phone: 517.371.8150
Fax: 517.367.7150
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www.fosterswift.com

FOSTER SWIFT

From: Mitchell, Desmond (LARA) [mailto:MitchellD6@michigan.gov]
Sent: Wednesday, November 17, 2021 4:36 PM
To: Russell, David; MCINTYRE Maria; Blair, Kevin M.
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully, Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotek.com; MILLS John
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

We've discussed it enough. We can continue to discuss it as the investigation continues. Also, the statements submitted do not provide any evidence that would support a delay in issuing a recall.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchelld6@michigan.gov

From: Russell, David <DRussell@fosterswift.com>
Sent: Wednesday, November 17, 2021 4:28 PM
To: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; MCINTYRE Maria <maria.mcintyre@biomerieux.com>; Blair, Kevin M. <KBlair@honigman.com>
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com; MILLS John <John.MILLS@biomerieux.com>
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Desmond – You stated earlier in your e-mail that if you were provided with the requested information that you would consider discussing it further. We have provided the information as requested that clearly shows that your tests do not warrant a recall. This is clearly not a health and safety issue. Please schedule a phone call to discuss with subject matter experts. Dave

David R. Russell

Attorney
Foster Swift Collins & Smith PC
313 S. Washington Square
Lansing, MI 48933
Phone: 517.371.8150
Fax: 517.367.7150
drussell@fosterswift.com
www.fosterswift.com

FOSTER SWIFT

From: Mitchell, Desmond (LARA) [<mailto:MitchellD6@michigan.gov>]
Sent: Wednesday, November 17, 2021 4:23 PM
To: MCINTYRE Maria; Russell, David; Blair, Kevin M.
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully, Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotek.com; MILLS John
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

All,

I appreciate the additional information, but no information has been provided that would prevent the recall. It will be issued today.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchelld6@michigan.gov

From: MCINTYRE Maria <maria.mcintyre@biomerieux.com>
Sent: Wednesday, November 17, 2021 4:03 PM
To: Russell, David <DRussell@fosterswift.com>; Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Blair, Kevin M. <KBlair@honigman.com>
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com; MILLS John <John.MILLS@biomerieux.com>
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Adding John Mills to the conversation.

1. Methods utilized have AOAC approval. This data collection usually includes robustness data that may or may not be a change in temperature. Please know, we are working to confirm if this data is available from the work for AOAC. This may take time to capture as I am collaborating with John Mills- Scientific Affairs Manager and Dr. Ron Johnson- former AOAC President.

2. ISO 17025 accreditation impacts the discussion as ISO sets the benchmark for the quality standards within accredited laboratories. If a recall is generated under these circumstances it's a reflection of a gap in ISO accreditation and does not relate to AOAC or the method itself. The lab has completed training on the method reflected in the training certificates and demonstrated via the ISO 17025 accreditation process.
3. When there is uncertainty in results either retesting or confirmation testing generally holds greater value than a multi-lab study. In such a study, there are many variable in the equation leading to variability.
4. The iso files have been reviewed and the assay appears to be running properly. The files have been transferred to the R&D team who created this assay for a 2nd opinion and to determine if other areas require addressing.

Kind regards,
Maria

Maria McIntyre
425-275-8013

From: Russell, David <DRussell@fosterswift.com>
Sent: Wednesday, November 17, 2021 11:59 AM
To: 'Mitchell, Desmond (LARA)' <MitchellD6@michigan.gov>; Blair, Kevin M. <KBlair@honigman.com>
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk <mfisk@byrumfisk.com> <mfisk@byrumfisk.com>; consulting@pmbbiotek.com; MCINTYRE Maria <maria.mcintyre@biomerieux.com>
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Desmond – I would ask for just a few more minutes. We have spoken with both Ms. McIntyre and Mr. Bird and they are working on sending those now. Thanks.

David R. Russell
Attorney
Foster Swift Collins & Smith PC
313 S. Washington Square
Lansing, MI 48933
Phone: 517.371.8150
Fax: 517.367.7150
drussell@fosterswift.com
www.fosterswift.com

FOSTER SWIFT

From: Mitchell, Desmond (LARA) [<mailto:MitchellD6@michigan.gov>]
Sent: Wednesday, November 17, 2021 1:48 PM
To: Blair, Kevin M.; Russell, David
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully, Risa (AG); Mark Fisk <mfisk@byrumfisk.com>; consulting@pmbbiotek.com
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

Kevin,

I can't wait until tomorrow. I'll give you until 3 pm. Also, you're aware that the absence of the logs is only part of the issue.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchelld6@michigan.gov

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Wednesday, November 17, 2021 1:39 PM
To: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Russell, David <DRussell@fosterswift.com>
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Desmond –

You said repeatedly yesterday that the absence of logs alone would not justify a recall. You pointed to the test results as the primary basis for warranting a recall. But recall that there are no test results at all related to Viridis North's results. At a minimum, Viridis North should be carved out of this recall. They are a separate licensee, with different ownership, and there is no reason they should get swept into this crippling recall just because their name also includes the word "Viridis."

Also, we are doing all we can to reconnect with Mr. Bird and Ms. McIntyre to get statements from them. They are tied up in other meetings and we haven't been able to reach them, but again, Mr. Bird has been copied on all these emails and we're confident that we have not misrepresented his views. We are asking that you give us until 8:30 tomorrow to get those statements. The stakes here couldn't be any higher, and we urge you not to rush forward with this simply because these folks weren't instantaneously available to drop everything and write statements.

Kevin

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

From: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>
Sent: Wednesday, November 17, 2021 12:52 PM
To: Russell, David <DRussell@fosterswift.com>; Blair, Kevin M. <KBlair@honigman.com>

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

[EXTERNAL EMAIL]

Have them submit those exact statements to me in writing and I'll consider discussing it further.

Also, that's not evidence my staff leaked it.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchelld6@michigan.gov

From: Russell, David <DRussell@fosterswift.com>
Sent: Wednesday, November 17, 2021 12:45 PM
To: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Blair, Kevin M. <KBlair@honigman.com>
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Desmond,

I know Kevin is driving, and this is extremely important, so I want to respond immediately. We have Mr. Bird, copied on this e-mail, and Marie McIntyre from bioMeriux that support our position that this recall is not appropriate. We are not sure how there could be any other explanation than retaliation when you have Mr. Bird stating this recall is inappropriate and Ms. McIntyre from the manufacturer of the platform stating that these retests do not support your position and yet the MRA insists on moving forward. We would ask to at least have the opportunity to get everyone on a call to discuss. The stakes are way too big here to risk a miscommunication that you suggest in your e-mail below. Please remember that Mr. Bird has been copied on all of these e-mails. This will destroy Viridis.

We certainly have evidence that there are leaks. There are people that knew the August 10th start date from your recall notice, which is not public information, early this morning.

Please let me know if we can set up a call.

Dave

David R. Russell
Attorney
Foster Swift Collins & Smith PC
313 S. Washington Square
Lansing, MI 48933
Phone: 517.371.8150
Fax: 517.367.7150
drussell@fosterswift.com
www.fosterswift.com

FOSTER SWIFT

From: Mitchell, Desmond (LARA) [<mailto:MitchellD6@michigan.gov>]
Sent: Wednesday, November 17, 2021 12:24 PM
To: Blair, Kevin M.
Cc: Russell, David; gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully, Risa (AG); Mark Fisk (mfisk@byrumfisk.com); consulting@pmbbiotek.com
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

Kevin,

As I've repeatedly stated, no one at the MRA is angry with Viridis. We're just following through with our regulatory responsibilities.

As far as your allegation about staff leaking information regarding the recall, do you have any evidence to support it?

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchelld6@michigan.gov

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Wednesday, November 17, 2021 12:17 PM
To: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>
Cc: Russell, David <DRussell@fosterswift.com>; gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; consulting@pmbbiotek.com
Subject: Re: Follow up & Summary of test results & Draft Recall Bulletin

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I'm begging you to please get on teams or phone to discuss and try and find a way for cooler heads to prevail. We truly believe this would be a huge mistake. It's one of the biggest recalls ever in the country based on the flimsiest of reasons.

Also, we've heard from countless people in the industry this morning that already know precise details about this recall. They didn't get that info from us so you have at least one staff member so happy about this recall that they're leaking it to the industry beforehand. That alone should give you pause and reconsider the clear biases of some of those who are trying to convince you that this is a safety issue.

Sent from my iPhone

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

On Nov 17, 2021, at 11:46 AM, Mitchell, Desmond (LARA) <MitchellD6@michigan.gov> wrote:

[EXTERNAL EMAIL]

Good Morning Dave,

Thank you for the feedback. Please note the following:

1. Claire also spoke to Mr. Bird and I don't believe your statements are a full and accurate representation of his point of view.
2. I'm not comfortable with your proposed revisions. I believe our initial draft provides a more accurate representation of the situation to the public and consumers. As a result, the attached bulletin is the one that will be issued today.
3. The investigation is still ongoing. As part of that investigation, we'll determine if the recall should be expanded as you've indicated. If it does, we'll expand the recall. However, as Kevin has pointed out before this is a public health and safety issue and we need to act on this as soon as possible. I believe there is currently sufficient evidence for us to proceed.
4. The MRA is also open to and believes it is necessary to continue to have discussions after the recall is issued and hopefully prevent something like this from happening in the future.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs
Telephone: (517) 243-9463
Email: mitchellD6@michigan.gov

From: Russell, David <DRussell@fosterswift.com>
Sent: Wednesday, November 17, 2021 9:55 AM
To: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; KBlair@honigman.com
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Hunt-Scully, Risa (AG) <HuntScullyR@michigan.gov>; Mark Fisk (mfisk@byrumfisk.com) <mfisk@byrumfisk.com>; 'consulting@pmbbiotek.com' <consulting@pmbbiotek.com>
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

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Good morning, Desmond.

In conversations yesterday and today with Pat Bird, a consultant with the AOAC, Mr. Bird has confirmed to Viridis that not having sample incubation times tracked is not a divergence from the approved AOAC method. Further, Mr. Bird agreed that use of the 10 sample tests sent to five different laboratories is not an appropriate method to confirm Viridis' testing for *Aspergillus* and an improper reason to issue a recall. Additionally, Viridis has had conversations with Marie McIntyre from bioMeriux and she too has opined that the MRA's use of the 10 sample tests is not a proper way to confirm Viridis' retests. I have copied Pat Bird on this e-mail, so he can confirm our conversation if necessary or answer any questions that you may have. It is my understanding that Mr. Bird called Ms. Patterson this morning to discuss this matter and he has indicated a willingness to speak to you as well.

Notwithstanding the fact that Viridis strongly disagrees that any recall is appropriate, at your request, I'm attaching clean and redline versions of your proposed recall bulletin with our proposed changes. While we strongly disagree with your analysis and decision to issue this recall, we respectfully submit that if health and safety is truly your main concern, you can accomplish the exact same result without all the alarmist and defamatory language you included in the first draft. We also truly don't understand why the scope of this recall includes all products (except inhalable concentrates). The proposed recall would encompass approximately 64,489 lbs. of flower (not counting trim, concentrates, etc.) over this period and using the average retail price per lbs. would total \$229,645,329.

All of our discussions thus far have focused on *aspergillus*, and yet this recall is essentially saying you don't trust any test results at all from Viridis (even products that were tested only for terpenes, potency, or other tests that have nothing to do with *aspergillus* tests). Therefore, any recall should focus solely on *aspergillus* results. As we discussed yesterday, 8/10 has no logical connection to the *aspergillus* test issues, and if the absence of logs alone justifies a recall, this recall should cover everything Viridis has tested for *aspergillus* since 2019. If, on the other hand, the recall is based on the competitors' test results, then the earliest collection date is 9/13.

Second, we respectfully urge you again to reconsider. This is a truly unprecedented and illogical recall. When Iron Laboratories was caught red handed falsifying records and deceiving consumers about the presence of dangerous pesticides, the MRA said it "has not been made aware of any adverse product reactions in conjunction with product tested by Iron Laboratories and is not recalling any marijuana product at this time." In contrast here, Viridis has been performing these tests for two years with the MRA's full knowledge, the MRA has observed these tests countless times and never said a word about not having incubator timing logs until 10/26/21. As soon as the MRA raised this issue, Viridis agreed to begin keeping these logs. And even after the MRA first raised this on 10/26, you waited another 3 weeks to issue the recall. You said yesterday that you were waiting for test results, but Metrc shows that all but a few of the tests were completed by 11/1. It's hard to understand why the MRA waited 15 days to issue a recall if this was truly a health and safety issue. We also discussed yesterday how four of the ten labs' results were consistent with Viridis' results, and yet it appears this recall is targeting Viridis only, and not those other labs. At a minimum, this should be a 3-lab recall since The Spot and Can-Lab both got the exact same result as Viridis (passed a sample with two consecutive negative tests after the sample was initially failed and not remediated). Also, we have been in contact

with A2LA, AOAC, and bioMerieux, who are all reviewing the data and have expressed serious concerns about your purported basis for this recall. I urge you again to let Viridis re-test these samples, or have an independent third party re-test them, or do an inter-lab test, or a proficiency test, or whatever test you want. Rushing into this recall on such flimsy, ill-advised rationale would be a colossal mistake that would cripple Viridis' business, wreak havoc on the entire industry, and raise serious questions about the MRA's integrity overall.

Finally, while we are sincerely interested in having further discussions and exploring any possible alternatives to this recall, we just want to reiterate that we feel like you've backed Viridis into a corner here and if you issue this recall, they will have no choice but to issue a press release to set the record straight and try to mitigate the damage from this ill-advised and completely illogical recall. We sincerely hope that won't be necessary, but we honestly don't feel like we have any other choice at this point unless the MRA drops this recall threat and starts working with us collaboratively to address the substance of your concerns. (It is well documented that we have been trying to have that dialogue with your staff since August to no avail; instead, it seems some have been spending all their time determined to find any potential reason to justify a recall).

Thank you,

Dave

David R. Russell

Attorney

Foster Swift Collins & Smith PC

313 S. Washington Square

Lansing, MI 48933

Phone: 517.371.8150

Fax: 517.367.7150

drussell@fosterswift.com

www.fosterswift.com

From: Mitchell, Desmond (LARA) [<mailto:MitchellD6@michigan.gov>]

Sent: Tuesday, November 16, 2021 4:57 PM

To: KBlair@honiigman.com

Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Russell, David; Hunt-Scully, Risa (AG)

Subject: FW: Follow up & Summary of test results & Draft Recall Bulletin

Importance: High

Kevin,

- I apologize for the delay. I've attached the recall bulletin for your review. Please provide any feedback or suggested revisions by 10 am on 11/17/2021. We'll review any proposed revisions and let you know if they will be adopted.
- Please see Claire's responses to your questions below.

If you have any questions, let me know. Thank you.

Desmond Mitchell, Operations Director
Marijuana Regulatory Agency
Department of Licensing and Regulatory Affairs

Telephone: (517) 243-9463
Email: mitchelld6@michigan.gov

From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Tuesday, November 16, 2021 10:58 AM
To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>
Cc: Mitchell, Desmond (LARA) <Mitchelld6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; drussell@fosterswift.com
Subject: RE: Follow up & Summary of test results

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Thank you for correcting that. I mean that sincerely. I appreciate you taking the time to triple check and correct that info. I just want to note, though, that the stakes here couldn't be any bigger. We're talking about health and safety, and we're here on the precipice of an enormous potential recall (that would cripple Viridis and raise serious questions about the integrity of the entire process) and one of the key data points that got us here wasn't just wrong in the initial chart, you also confirmed it again this morning via email. It wasn't until the third check that mistake was finally realized.

Also, I think it's critical to consider how many of the tests corroborate Viridis's samples. Just based on the "pass" results alone, that's 4 out of ten that are consistent with Viridis's results (and several of the other 6 were tested by competitors who have publicly talked about trying to put Viridis out of business, so how do you account for that obvious bias?).

For the retests in question, and for the sake of this conversation, we will exclude the test performed by Infinite because that sample should have been passing. This sample may be viewed as a control, in this case, and should rightly be excluded from any further data analysis.

With all this considered:

- Viridis performed 8 retests and passed 100% of them, failing 0% of the retests.
- Of the additional 8 retests performed by 4 separate facilities, 6 failed. That leaves us with a 25% passing rate and a 75% failure rate. This level of uncertainty is enough cause for concern.
- Regardless of competition, all scientists should be well versed in the ethical conduct of research. If they are not, they also are aware that all raw data and all data, in fact, is subject to scrutiny by the agency. I have no concerns about bias as the licensees were not told that this investigation had anything to do with Viridis. All labs were simply directed to pick up samples from the lab and from the grow. This is commonplace in all investigations that require retesting and does not single out the lab in particular as being part of the investigation.

Further, if any of the "fail" or "set to fail" cells had any test(s) pass, that's very important information to consider. If there was one pass and one fail, I understand that would be a fail under the rules. But if you're truly making data-driven decisions here, there shouldn't be any hesitation to share the data with us. If there were no negative tests associated with the "fail" or "set to fail" samples, why wouldn't you tell us that? And if there were, we'd like to know how many.

- I am not entirely sure of what you are asking in the case. Aside from the error that was corrected for sample number ending in -1014, all results are correct.
- There is no additional information to be provided here.
- If you are referring to an overall analysis of data, Viridis and Viridis North provide the 1st and 3rd most tests to the regulated market in Michigan.

- During this time of year, in particular, Aspergillus is incredibly common, with the average percentage of total flower packages tested resulting in an Aspergillus failure 9.43% of the time.
- The mean value on this data set is 7.42%.
- Despite the fact that Viridis and Viridis North perform the 1st and 3rd most tests in the state, they are only reporting aspergillus failures for 0.78% and 4.9% of those samples, respectively. Given that they fall well under both the median and average values for reporting, the data is considered anomalous and is being treated as such.

Kevin M. Blair

HONIGMAN LLP
 O 517.377.0716
kblair@honigman.com

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Tuesday, November 16, 2021 10:27 AM
To: Blair, Kevin M. <KBlair@honigman.com>; Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>
Cc: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; drussell@fosterswift.com
Subject: RE: Follow up & Summary of test results

[EXTERNAL EMAIL]

All,

Upon confirmation with COAs and data, I have updated a sample from The Spott to reflect a passing status for package:

1A4050300009155000001014

Please note that package:

1A4050300009155000001015

Is set as fail, and the overall retest result is set to fail.

Thank you,

Claire Patterson

Manager, Scientific & Legal Section
 Enforcement Division
 Marijuana Regulatory Agency

(517) 230-2097
PattersonC8@michigan.gov
www.michigan.gov/MRA

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From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Tuesday, November 16, 2021 10:00 AM
To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>
Cc: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; drussell@fosterswift.com
Subject: RE: Follow up & Summary of test results

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Claire –

Have you had a chance yet to check whether the first sample retested by The Spott (ending in 1014) was a pass or fail? Your chart shows a fail, but it appears in METRC as a pass.

Also, is there a difference on your chart between the cells that say “fail” vs “set to fail”? For example, does “fail” mean they had two positive tests whereas “set to fail” might mean they had one positive and one negative? If so, that is important information and context for us and Desmond to know (i.e., some of these samples may have tested negative 3 out of 4 times).

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

From: Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Sent: Monday, November 15, 2021 1:38 PM
To: Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>; Blair, Kevin M. <KBlair@honigman.com>
Cc: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>
Subject: Follow up & Summary of test results

[EXTERNAL EMAIL]

Hi Greg,

As discussed on our call, I am attaching a summary of the test results for the tests in question.

All the best,

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

(517) 230-2097
PattersonC8@michigan.gov
www.michigan.gov/MRA

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Russell, David

From: Patrick Bird <consulting@pmbbiotek.com>
Sent: Wednesday, November 17, 2021 3:02 PM
To: Mitchell, Desmond (LARA); Blair, Kevin M.; Russell, David
Cc: gmichaud@viridisgrp.com; mglinn@viridisgrp.com; Kluytman, Julie (LARA); Patterson, Claire (LARA); Hunt-Scully, Risa (AG); Mark Fisk (mfisk@byrumfisk.com)
Subject: RE: Follow up & Summary of test results & Draft Recall Bulletin

Good afternoon all,

Apologies for the late response. I've reviewed the email thread and had the opportunity to speak with all parties today (Claire, Desmond, Viridis Group) and have included a statement below summarizing the key points from these conversations. I also want to emphasize that I am a contract employee with AOAC, so I can't speak on their behalf.

1. AOAC INTERNATIONAL's role in the cannabis industry is to develop standards and guidance to allow alternative methods to be certified through one of its conformity assessment programs. The certification of the method demonstrates its fit for purpose for use in that industry if the method is performed as written in the validation guidelines. AOAC is not involved in laboratory assessment and/or accreditation.
2. Determining if a laboratory is performing a method correctly falls on the accreditation organization that issues the ISO 17025 certificate. If a method is certified during the accreditation it demonstrates that the laboratory is competent to run that method. The MRA's decision to recall these products due to the lack of traceability of the incubation logs indicates an issue with the accreditation process and not AOAC's certification. In this instance, the lab has demonstrated they can competently perform the method through their accreditation, although we all acknowledge there is a gap in the data collection process that fully supports this.
3. The additional testing of materials at other labs is not something that I believe supports a recall as there are many factors in play that may have lead to the different results (same batch but different test portions analyzed, time gaps in analysis from one lab to another, etc).

Again I want to reiterate that these statements are on my own accord but the first one is in alignment with AOAC's stated policies and procedures.

Best regards

Pat Bird

Patrick M. Bird

Principal Consultant of PMB BioTek Consulting
AOAC INTERNATIONAL Technical Consultant
330-730-8741
consulting@pmbbiotek.com



PMB BioTek Consulting

From: Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>
Sent: Wednesday, November 17, 2021 11:48 AM
To: Blair, Kevin M. <KBlair@honigman.com>; Russell, David <DRussell@fosterswift.com>

Complaint, Ex. L



Method Approval Report

VALIDATION STATUS: (Approved / Not Approved)		METHOD NAME / SOP NUMBER: LOM 20 Detection of Aspergillus by Gene- Up/LOM 21 Detection of Salmonella and STEC by GENE-UP/LOM 22 TEMPO YM/CC	
FACILITY NAME Viridis Lansing		REVIEW DATE 08/05/2021	COUNTY Ingham
ADDRESS 2827 E. Saginaw St.		FACILITY TYPE Safety Compliance Facility/Marihuana Safety Compliance Facility	INSPECTION NUMBER SC-00009/AU-SC-000113
CITY, STATE ZIP CODE Lansing, MI 48912		FACILITY REPRESENTATIVE Michele Glinn	ASSIGNED AGENT LSS Rosenzweig
		FACILITY PHONE 833-847-4347	

INSPECTOR NOTES:

☐ STATUS (08/10/2021):

- Approved for all analyses listed below on ALL MATRICES
(flower, infused, concentrate):

- Potency
- Water Activity
- Moisture Content
- Chemical Residue
- Metals
- Foreign Matter
- Microbials
- Residual Solvent Analysis
- Target Analytes
- Terpenes

1. POTENCY

SOP: 7.1a Cannabinoid Analysis by UHPLC-DAD

Matrix: Flower

Instrument(s): Thermo Vanquish UHPLC System with VF-P10-A UHPLC pump and a Diode Array Detector (DAD) Lightpipe™ VH-D10, with a Restek sub-2 micron UHPLC column (Raptor ARC-18 LC Column 1.8 μm 100 x 3.0 mm)

PT Results:

1/03/2020 – External Flower PT – non-matrix match (standard)

Method Approval Report

- Analytes: Delta9THC; CBD; CBDA; Delta9THCA; CBG; Delta8THC; THCV; CBDV; CBGA; CBC; CBDVA
- All results **ACCEPT**

3/12/2020 – External Hemp Oil PT – (standard)

- Analytes: Delta9THC; CBD; CBDA; Delta9THCA; CBG; Delta8THC; THCV; CBDV; CBGA; CBC; CBDVA
- All results **ACCEPT**

05/12/2020 – Gummy Matrix PT – (standard)

- Analytes: Delta9THC; CBD; CBDA; Delta9THCA; CBN; CBG; Delta8THC; THCV; CBDV; CBGA; CBC
- All results **ACCEPT**

Comments (4/16/2020):

- i. Method submitted and accepted on 01/24/2020 for analyses as written on Flower Matrix (ONLY)
- ii. Passing proficiency test submitted to the agency on 4/2/2020 Method Approved for analysis of concentrates.

Updates submitted: 7/08/2020

- *Potency approved on all matrices*

2. WATER ACTIVITY

SOP: 7.3 Moisture Content and Water Activity Analysis

Matrix: Flower

PT Results:

- PT – Flower - 01/03/2020 Water Activity – **ACCEPT**
- PT – Gummy - 03/11/2020 Water Activity - **ACCEPT**

Comments (4/10/2020):

- iii. Method submitted and accepted on 01/03/2020

Updates submitted:

3. MOISTURE CONTENT

SOP: 7.3 Moisture Content and Water Activity Analysis

Matrix: Flower

PT Results:

Acceptable PT is not required

Comments (4/16/2020):

- iv. Method submitted and accepted on 10/25/2019
- v. Not required on concentrates

Updates submitted:

4. CHEMICAL RESIDUE

SOP: 7.4a Chemical Residue / Pesticide Analysis by LC-MS/MS

Matrix: Flower

Instruments:

1. ThermoFisher Q Exactive Focus Hybrid Orbi-Trap Mass Spectrometer with Vanquish Binary UHPLC and Tracefinder software

August 21, 2020 – Added Instrument:

2. AB Sciex 6500 Triple Quadrupole LC-MS/MS with Exion liquid chromatograph and interchangeable ESI and APCI probes
 3. OS-Q MS Data Analytics processing software
- Note: Licensee has submitted appropriate validation and proficiency tests*

PT Results:

2/21/2020 and 2/22/2020 Analyzed in solvent

- All analytes **ACCEPT**.

4/6/2020 Analyzed in hemp oil matrix – BLIND SAMPLE ANALYSIS

- All unknown target analytes **ACCEPT**.

7/01/2020 Analyzed in gummy matrix

- All unknown target analytes **ACCEPT**.

Comments (4/16/2020):

- vi. Method submitted and accepted on 01/24/2020 in Flower Matrix
- vii. Passing PT submitted as Blind Sample analysis, submitted to agency on 4/16/2020. Method approved for analysis of concentrates.

5. METALS

SOP: 7.2 Heavy Metal Analysis

Matrix: Flower; Concentrate

Instruments: ThermoFisher iCAP RQ ICP-MS with PrepFast injector port
prepFAST 4DX by Elemental Scientific
MARS6 Microwave-assisted acid digestion extraction system

PT Results:

1/03/2020 – External Flower PT – (hemp)

- Chromium; Nickel; Arsenic; Cadmium; Mercury; Lead
- All results: **ACCEPT**

3/12/2020 – External Hemp Oil PT – (hemp)

- Chromium; Nickel; Copper; Arsenic; Cadmium; Mercury; Lead
- All results: **ACCEPT**

3/24/2020 – Gummy Matrix PT

- Chromium; Arsenic; Cadmium; Mercury; Lead
- All results: **ACCEPT**

Comments:

- viii. **10/25/2019:** Method approved as written for flower matrix.
- ix. **01/24/2020:** Nickel and Copper added to previously approved method on flower matrix
- x. **04/16/2020:** Method approved for use on concentrate matrix
- xi. **04/28/2021** SMPR published 02/11/2021, the current method does not meet the SMPR requirements for the following analytes and will need to be updated: Lead, Mercury, and Cadmium before August 11, 2021.
- xii. **07/2/2021** Under Method Details Specimen Type is cannabis flower, but under Recovery it states: One cannabis flower sample in each run was analyzed in duplicate, with one aliquot used as the unspiked and one as the spiked sample. Gummies were purchased from a local grocery store. Please provide details on cannabis flower and associated metric tag numbers and results from gummy verification if seeking approval.
- xiii. **07/15/2021** Method now meets the SMPR requirements for Lead, Mercury, and Cadmium

Updates submitted:

Updates submitted:

07/15/2021 Provided details on cannabis flower and associated metric tag numbers and removed reference to gummies.

6. RESIDUAL SOLVENTS

SOP: 7.10 Residual Solvent Analysis

Matrix: Concentrate

PT Results:

4/14/2020 – External Hemp Oil PT – (hemp)

- All analytes present
- All results: **ACCEPT**

Comments (05/04/2020):

xiv. Method approved as written on concentrate matrix only.

SOP: 7.7 Terpenoid Analysis

Matrix: All

PT Results:

06/18/2020 – External Hemp Oil PT – (hemp)

- xv. a-Bisabolol, a-humulene, a-pinene, a-terpinolene, b-caryophyllene, myrcene, b-pinene, caryophyllene oxide, limonene, linalool.
- xvi. a-pinene, a-terpinolene, b-caryophyllene, myrcene, b-pinene, caryophyllene oxide, limonene: **ACCEPT**
- xvii. a-Bisabolol, a-humulene, linalool: **NOT ACCEPT**

Comments (09/01/2020): Terpene Analysis Added

- i. Method approved as written for the analysis of all terpenes listed below:
a-pinene, a-terpinolene, b-caryophyllene, myrcene, b-pinene, caryophyllene oxide, limonene: **ACCEPT**
- ii. The method may be approved for the following terpenes (below) when an acceptable PT is reported.
a-Bisabolol, a-humulene, linalool: **NOT ACCEPT**

04/28/2021 SMPR published 02/11/2021, the current method does not meet the SMPR requirements for the following analytes and will need to be updated: Ethanol, Heptane, Hexanes all isomers, 2,2-Dimethylbutane, 2,3-Dimethylbutane, 2-Methylpentane, 3-Methylpentane, Isopropyl alcohol, Methanol, Propane, Toluene and Total xylenes (ortho-, meta-, para-) before August 11, 2021.

07/23/2021 Method now meets the SMPR requirements for Ethanol, Heptane, Hexanes all isomers, 2,2-Dimethylbutane, 2,3-Dimethylbutane, 2-Methylpentane, 3-Methylpentane, Isopropyl alcohol, Methanol, Propane, Toluene and Total xylenes (ortho-, meta-, para-).



Updates submitted:

Updates submitted:

07/23/2021 Verification report for recovery of Ethanol, Heptane, Hexanes all isomers, 2,2-Dimethylbutane, 2,3-Dimethylbutane, 2-Methylpentane, 3-Methylpentane, Isopropyl alcohol, Methanol, Propane, Toluene and Total xylenes (ortho-, meta-, para-).

7. MICROBIAL ANALYSIS

SOP: 7.8 Plant-Micro DNA Extraction from Plant Material, LOM - 7.17 Total Yeast and Mold Plating and Count

LOM 20 Detection of Aspergillus by Gene-Up/LOM 21 Detection of Salmonella and STEC by GENE-UP/LOM 22 TEMPO YM/CC

Matrix: Flower

Instrumentation: Medicinal Genomics protocol as written and AriaMax

PT Results:

Flower – Hemp flower Matrix

APC (PCR- Quantitative) 10/21/2019 – ACCEPT

Total Coliform (PCR- Quantitative) 10/21/2019 – ACCEPT

E. coli (non-STEC) (PCR- Quantitative) 10/21/2019 – ACCEPT

Enterobacteriaceae (PCR- Quantitative) 10/21/2019 – ACCEPT

Yeast/Mold (PCR- Quantitative) 10/21/2019 – ACCEPT

Yeast and Mold (Plating) 2/01/2021 – ACCEPT

Concentrate – Hemp oil Matrix

Salmonella (PCR- Qualitative) 04/01/2020 – ACCEPT

Coliform (PCR): Externally Graded Not submitted, internal submitted– ACCEPT

Yeast and Mold (PCR): Externally Graded Not submitted, internal submitted– ACCEPT

STEC (PCR- Qualitative) 04/01/2020- ACCEPT

Total Mold (PCR- Qualitative): Externally Graded Not submitted, internal submitted– ACCEPT

Concentrate – Chocolate Matrix

Salmonella (PCR- Qualitative) 05/06/2020 – ACCEPT



Method Approval Report

STEC (PCR- Qualitative) 05/06/2020- ACCEPT

CMPT-028B Qualitative STEC in Hemp – Viridis Laboratories - NSI Lab Solutions/ FM-PTX1037

Analyte#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1 7034	Ecoli STEC	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/19/21	David Chalmers
Sample 2 7034	Ecoli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample 3 7034	Ecoli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample 4 7034	Ecoli STEC	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/19/21	David Chalmers
Sample 5 7034	Ecoli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers

CMPT-029B Qualitative STEC in Edible – Viridis Laboratories - NSI Lab Solutions/ FM-PTX1037

Analyte#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1 7034	Ecoli STEC	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/19/21	David Chalmers
Sample 2 7034	Ecoli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample 3 7034	Ecoli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample 4 7034	Ecoli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample 5 7034	Ecoli STEC	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/19/21	David Chalmers

CMPT-030B Qualitative STEC in Oil – Viridis Laboratories - NSI Lab Solutions/ FM-PTX1037

Analyte#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1 7034	Ecoli STEC	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/19/21	David Chalmers
Sample 2 7034	Ecoli STEC	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/19/21	David Chalmers
Sample 3 7034	Ecoli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample 4 7034	Ecoli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers
Sample 5 7034	Ecoli STEC	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/19/21	David Chalmers



Method Approval Report

CMPT-025B Quantitative Salmonella in Hemp – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyte#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1 2057	Salmonella	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/14/21	David Chalmers
Sample 2 2057	Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers
Sample 3 2057	Salmonella	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/14/21	David Chalmers
Sample 4 2057	Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers
Sample 5 2057	Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers

CMPT-026B Qualitative Salmonella in Edible – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyte#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1 2057	Salmonella	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/14/21	David Chalmers
Sample 2 2057	Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers
Sample 3 2057	Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers
Sample 4 2057	Salmonella	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/14/21	David Chalmers
Sample 5 2057	Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers



Method Approval Report

CMPT-027B Qualitative Salmonella in Oil – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyst#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1 2057	Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers
Sample 2 2057	Salmonella	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/14/21	David Chalmers
Sample 3 2057	Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers
Sample 4 2057	Salmonella	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/14/21	David Chalmers
Sample 5 2057	Salmonella	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/14/21	David Chalmers

CMPT-031B Qualitative Aspergillus Molds in Hemp – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyst#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1 6095	Total Mold	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 2 6095	Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3 6095	Total Mold	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 4 6095	Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5 6095	Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 1 6096	A. fumigatis	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2 6096	A. fumigatis	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3 6096	A. fumigatis	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4 6096	A. fumigatis	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5 6096	A. fumigatis	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers

Method Approval Report

Sample 1 6097 A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2 6097 A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3 6097 A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4 6097 A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5 6097 A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 1 6098 A. brasiliensis (Niger)	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 2 6098 A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3 6098 A. brasiliensis (Niger)	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 4 6098 A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5 6098 A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 1 6099 A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2 6099 A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3 6099 A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4 6099 A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5 6099 A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers

QMPT-0328 Qualitative Aspergillus Molds in Edible – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyses#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1 6095 Total Mold		Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 2 6095 Total Mold		Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3 6095 Total Mold		Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4 6095 Total Mold		Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5 6095 Total Mold		Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 1 6096 A. fumigatus		Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2 6096 A. fumigatus		Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3 6096 A. fumigatus		Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4 6096 A. fumigatus		Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5 6096 A. fumigatus		Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 1 6097 A. flavus		Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2 6097 A. flavus		Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3 6097 A. flavus		Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4 6097 A. flavus		Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5 6097 A. flavus		Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers



Method Approval Report

Sample 1 6098	A. brasiliensis (Niger)	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 2 6098	A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3 6098	A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4 6098	A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5 6098	A. brasiliensis (Niger)	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 1 6099	A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2 6099	A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3 6099	A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4 6099	A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5 6099	A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers

CMPT-033B Qualitative Aspergillus Molds in Oil – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyte#	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Evaluation	Analysis Date	Analyst's Name
Sample 1 6095	Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2 6095	Total Mold	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 3 6095	Total Mold	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 4 6095	Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5 6095	Total Mold	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers



Method Approval Report

Sample 1 6096 A. fumigatus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2 6096 A. fumigatus	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 3 6096 A. fumigatus	Gene Up	PCR	PRESENT	PRESENT	ACCEPT.	07/16/21	David Chalmers
Sample 4 6096 A. fumigatus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5 6096 A. fumigatus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 1 6097 A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2 6097 A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3 6097 A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4 6097 A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5 6097 A. flavus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 1 6098 A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2 6098 A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3 6098 A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4 6098 A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5 6098 A. brasiliensis (Niger)	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 1 6099 A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 2 6099 A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 3 6099 A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 4 6099 A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers
Sample 5 6099 A. terreus	Gene Up	PCR	ABSENT	ABSENT	ACCEPT.	07/16/21	David Chalmers

CMPT-040B Quantitative Yeast/Mold in Hemp – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyst	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Units	Acceptance Limits	Evaluation	Analysis Date	Analyst's Name
6057	Yeast/Mold	Tempo	MPN Tempo Biomerieux	210000	206000	cfu/g	82400 - 330000	ACCEPT.	06/29/21	David Chalmers

CMPT-059B Quantitative Yeast/Mold in Edible – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyst	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Units	Acceptance Limits	Evaluation	Analysis Date	Analyst's Name
6057	Yeast/Mold	Tempo	MPN Tempo Biomerieux	32000	35200	cfu/g	14100 - 56000	ACCEPT.	06/29/21	David Chalmers

CMPT-038B Quantitative Coliforms and E.coli in Edible – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyst	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Units	Acceptance Limits	Evaluation	Analysis Date	Analyst's Name
6053	Total Coliform	Biomerieux Tempo	MPN	940000	227605	cfu/g	94100 - 507900	ACCEPT.	06/29/21	David Chalmers

CMPT-037B Quantitative Coliforms and E.coli in Hemp – Viridis Laboratories - NSI Lab Solutions/ FM-PTX995

Analyst	Analyte	Method Technology	Method Description	Reported Value	Assigned Value	Units	Acceptance Limits	Evaluation	Analysis Date	Analyst's Name
6053	Total Coliform	Biomerieux Tempo	MPN	480000	463000	cfu/g	185000 - 741000	ACCEPT.	06/29/21	David Chalmers

Comments (4/16/2020):



Method Approval Report

- iii. **1/03/2020:** Method approved as written. NOTE: Please submit upper level of quantitation for quantitative pcr methodology.
- iv. **1/24/2020:** ULOQ submitted in 01/21/2020 remediation response.
- v. **4/16/2020:** Method approved as written on concentrate matrix.
- vi. **04/28/2021:** The method for *Aspergillus*, *Salmonella*, and STEC does not meet the current SMPR's the agency published 02/11/2021, the facility will not be able to use this method after 08/11/2021.
- vii. **7/27/2021:** This review is only for the qualitative detection of *Aspergillus* spp. *Salmonella* spp. and STEC producing *Escherichia coli*. Raw data was not included with the validation report. Please include amplification curve and melt-curve raw data. Please include package insert for all assays referenced for MRA review. Please provide detailed information on thermocycler instrumentation, the manufacturer and model number. Humidity and temperature may interfere with the performance of the thermocycler instrument. Please include thermocycler manual to determine temperature range (°C) and relative humidity range (non-condensing). Please include environmental monitoring controls for the room where the testing will be conducted and an acceptable range for each on the log. Additionally, the bench log/worksheet should include information on the PCR plate well ID associated with test samples and controls. Please include the bench log/worksheet. Please include MRA acceptance criteria in SOPs.

This review is only for verification of total Coliform enumeration and total yeast and mold enumeration. Raw data was not included with the validation report. Please include raw data from either a .ted (TEMPO file) converted to .pdf, or .csv (Excel) file type. Please include package insert for all assays referenced for MRA review. Please provide detailed information on TEMPO instrumentation, the manufacturer and model number. If Humidity and temperature may interfere with the performance of the TEMPO instrument, please include TEMPO manual to determine temperature range (°C) and relative humidity range (non-condensing). Please include environmental monitoring controls for the room where the testing will be conducted and an acceptable range for each on the bench log/worksheet. Additionally, the log/worksheet should include information on how ID# associated with test samples and controls are logged. Please include the bench log sheet. Please include MRA acceptance criteria in SOPs.

- viii. **8/03/2021:** This review is only for the qualitative detection of *Aspergillus* spp. *Salmonella* spp. and STEC producing *Escherichia coli*. Please include amplification curve and melt-curve raw data for the *Aspergillus* spp. verification, data provided (beverage) was not from the matrices used in the verification study. Please include package insert for all assays referenced for MRA review, these should be available from the manufacturer's website directly. Humidity and temperature may interfere with the performance of the thermocycler instrument. Please include thermocycler manual to determine temperature range (°C) and relative humidity range (non-condensing).

This review is only for verification of total Coliform enumeration and total yeast and mold enumeration. Please provide detailed information on TEMPO instrumentation, specifically if Humidity and temperature may interfere with the performance of the TEMPO instrument, please include TEMPO Reading Station User's Manual (only quick start guides were provided) which includes General Characteristics with Environmental Considerations to determine operational temperature range (°C) and relative humidity range (non-condensing).

- ix. **8/10/2021:** The validation submitted for verification for the qualitative detection of *Aspergillus* spp., *Salmonella* spp. and STEC producing *Escherichia coli* method is thorough and satisfactorily addresses all requirements outlined in the Safety Compliance Facility Testing Guide.

The validation submitted for quantitative detection of total yeast and mold method is thorough and satisfactorily addresses all requirements outlined in the Safety Compliance Facility Testing Guide.



Method Approval Report

These methods are provisionally approved pending the results of the 09/13/2021-09/15/2021 ISO scope expansion.

Updates submitted

Updates submitted:

8/03/2021: Included environmental monitoring controls for the room where the testing will be conducted and an acceptable range for each on the log. Included information on the PCR plate well ID associated with test samples and controls. Included the bench log/worksheet. Included MRA acceptance criteria in SOPs.

8/05/2021: Included amplification raw data for the *Aspergillus* spp. verification, package insert for all assays and thermocycler manual. Provided detailed information on TEMPO Reading Station

8. FOREIGN MATTER

SOP: 7.11 Foreign Matter Analysis and Photographic Image

Matrix: Flower

PT Results: 2/27/2020 – External Flower PT – (hemp)

- Visual analysis, filth/extraneous material \geq / \leq 5% - ACCEPT

Comments (4/16/2020):

xx. 4/16/2020: Method Approved: Concentrate and Flower Matrix

Updates submitted:

9. TARGET ANALYTES

SOP: LOM 7.14 Vitamin E Acetate Analysis by UHPLC-DAD

Matrix: Concentrate

PT Results:

- Vitamin E Acetate (05/04/2020)- ACCEPT

Comments:

07/08/2020: The MRA is notifying the laboratory that analyzing Vitamin E Acetate on UHPLC-DAD has the potential to result in false positive results due to matrix interference and misidentification of peaks. The occurrence of false negative results has not yet been demonstrated but is also hypothesized due to matrix interference. The laboratory is aware of potential interferences.

Updates submitted:

SOP: LOM 7.15 Vitamin E Acetate Analysis by LC-MS/MS

Matrix: Concentrate



Method Approval Report

PT Results:

- Vitamin E Acetate (10/23/2020)- ACCEPT

Comments:

10/30/2020: Laboratory submitted validation documents for addition of Vitamin E Acetate. Approved on 5/20/2020. The laboratory previously performed analysis of Vitamin E Acetate using an HPLC-DAD. The laboratory submitted an alternate protocol to detect Vitamin E Acetate using LC-MS/MS and will use this method going forward and use HPCL-DAD as a backup protocol.

ADDITIONAL ANALYSES – NOT REGULATED BY THE MRA

This section serves as acknowledgement that the laboratory has provided the MRA with the appropriate documentation and has notified the agency that they will be performing these analyses. The MRA does not require the following analyses.

- I. Plant Gender Identification – Acknowledged.

All changes, updates, or additions to methodology must be submitted to the MRA for review and approval.

Assigned MRA Representative:

NAME: Claire T. Patterson, LSS Rosenzweig
ADDRESS: 2407 North Grand River Ave., Lansing, MI 48906
TELEPHONE: 517-230-2097, 517-243-4395
E-MAIL: RosenzweigN@michigan.gov

Rule 5(1) of the Sampling and Testing rule set (R. 420.305) A laboratory shall do all of the following: (a) Become fully accredited to the International Organization for Standardization (ISO), ISO/IEC 17025:2017 by an International Laboratory Accreditation Cooperation (ILAC) recognized accreditation body or by an entity approved by the agency within 1 year after the date the laboratory license is issued and agree to have the inspections and reports of the International Organization for Standardization made available to the agency.

If any of the methods on this approval report are not accredited by the expiration of the license, the approvals are rescinded in accordance with the rule above.

Complaint, Ex. M



PUBLIC HEALTH AND SAFETY BULLETIN

November 17, 2021

Notification of Marijuana Product Recall

The Marijuana Regulatory Agency (MRA) has identified inaccurate and/or unreliable results of products tested by safety compliance facilities Viridis North, LLC and Viridis Laboratories, LLC.

In the interest of public health and safety, the MRA is issuing this health and safety advisory bulletin for **all** marijuana products tested by Viridis Laboratories, LLC (license numbers SC-000009 and AU-SC-000113) and Viridis North, LLC (license numbers SC-000014 and AU-SC-000103) **except** for inhalable marijuana concentrate products such as:

- Vape carts.
- Live resin.
- Distillate.
- Any other cannabis concentrate created through residual solvent extractions.

The marijuana products impacted have a test date between August 10, 2021 and November 16, 2021. All marijuana product labels are required to list the name and license number of the safety compliance facility that conducted the testing and date the product was tested.

Note: An MRA investigation is still on-going.

Consumers who have marijuana products in their possession that meet the recall criteria may return the products to the marijuana sales location where they were purchased for proper disposal. Consumers with weakened immune systems or lung disease are at the highest risk for health-related incidents such as aspergillosis, which can impact lung function, if these potentially harmful products are consumed.

Consumers who have experienced adverse reactions after using these products should report their symptoms and product use to their physician. Consumers are requested to report any adverse product reactions to the MRA via email: MRA-Enforcement@michigan.gov or via phone: 517-284-8599.

Marijuana sales locations that sold product covered by this bulletin must display this recall notice on the sales floor, visible to all customers, for 30 days from the date of this

This advisory bulletin does not constitute legal advice and is subject to change. Licensees are encouraged to seek legal counsel to ensure their operations comply with the Medical Marijuana Facilities Licensing Act and associated Administrative Rules.



PUBLIC HEALTH AND SAFETY BULLETIN

November 17, 2021

notice. Marijuana sales locations that receive adverse product reactions from consumers should report the adverse product reactions to the agency at MRA-Enforcement@michigan.gov and document these reports in METRC.

Licensees with products remaining in their inventory that meet the recall criteria have the following options:

- Destroy the product and provide proof of destruction: MRA-Compliance@michigan.gov.
- Have the product retested for the microbials compliance panel.
- Send the product back to the original licensee source so they can destroy or have the product retested as a larger batch.

Licensees that opt to have product sent back or retested will need to create new METRC packages with new METRC identification numbers prior to transferring or submitting the products for testing. Additional guidance can be provided to licensees who need assistance in creating these packages by reaching out to MRA-Compliance@michigan.gov.

Additional questions can be sent to the MRA's Operations Support Section: MRA-Compliance@michigan.gov.

Complaint, Ex. N

From: Patterson, Claire (LARA) [<mailto:PattersonC8@michigan.gov>]
Sent: Thursday, November 18, 2021 12:06 PM
To: Blair, Kevin M.; Kluytman, Julie (LARA); Mitchell, Desmond (LARA); MRA-scf
Cc: Todd Welch; Gregoire Michaud; Michele Glinn; Russell, David; Michael LaFramboise
Subject: RE: Tomorrow

The attached approval refers to Aspergillus testing only.

Claire Patterson

Manager, Scientific & Legal Section
Enforcement Division
Marijuana Regulatory Agency

(517) 230-2097
PattersonC8@michigan.gov
www.michigan.gov/MRA



Spread Hope
GET VACCINATED
Save Michigan Lives.

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From: Blair, Kevin M. <KBlair@honigman.com>
Sent: Thursday, November 18, 2021 12:04 PM
To: Kluytman, Julie (LARA) <KluytmanJ@michigan.gov>; Mitchell, Desmond (LARA) <MitchellD6@michigan.gov>; MRA-scf <MRA-scf@michigan.gov>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>
Cc: Todd Welch <twelch@viridisgrp.com>; Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>; Russell, David <DRussell@fosterswift.com>; Michael LaFramboise <mlaframboise@viridisgrp.com>
Subject: FW: Tomorrow

CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

Following up on my last email, see highlighted language below as one example when Viridis was explicitly told they could resume testing. Viridis communicated that to customers based on the MRA's assurances and now it seems the MRA is contradicting what you said yesterday. Again, we need to get on the phone ASAP please.

Kevin M. Blair

HONIGMAN LLP
O 517.377.0716
kblair@honigman.com

From: MRA-scf <MRA-scf@michigan.gov>
Sent: Tuesday, November 16, 2021 5:51 PM
To: Gregoire Michaud <gmichaud@viridisgrp.com>; Michele Glinn <mglinn@viridisgrp.com>
Cc: Blair, Kevin M. <KBlair@honigman.com>; Todd Welch <twelch@viridisgrp.com>;
drussell@fosterswift.com; Michael LaFramboise <milaframboise@viridisgrp.com>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Rosenzweig, Noah (LARA) <RosenzweigN@michigan.gov>
Subject: RE: Tomorrow

[EXTERNAL EMAIL]

Greg,

Thank you and Michele for promptly sharing the incubator log for Viridis. As discussed earlier, Viridis is approved to move forward using the updated LOM-7.20 Gene-Up Aspergillus. A current method approval form for Viridis is attached. We will also cease placing Viridis Aspergillus tests on administrative hold. If outstanding questions remain, please let me know.

Patrice R. Fields, Ph.D.

Laboratory Scientist Specialist
Scientific & Legal Section, Enforcement Division
Marijuana Regulatory Agency
517-281-3640
FieldsP2@michigan.gov
www.michigan.gov/MRA



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From: Gregoire Michaud <gmichaud@viridisgrp.com>
Sent: Tuesday, November 16, 2021 4:12 PM
To: MRA-scf <MRA-scf@michigan.gov>
Cc: KBlair@honigman.com; Todd Welch <twelch@viridisgrp.com>; drussell@fosterswift.com; Michele Glinn <mglinn@viridisgrp.com>; Michael LaFramboise <mలాframboise@viridisgrp.com>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Rosenzweig, Noah (LARA) <RosenzweigN@michigan.gov>
Subject: RE: Tomorrow

CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

See attached...thanks Patrice.

From: MRA-scf <MRA-scf@michigan.gov>
Sent: Tuesday, November 16, 2021 3:30 PM
To: Gregoire Michaud <gmichaud@viridisgrp.com>
Cc: KBlair@honigman.com; Todd Welch <twelch@viridisgrp.com>; drussell@fosterswift.com; Michele Glinn <mglinn@viridisgrp.com>; Michael LaFramboise <mలాframboise@viridisgrp.com>; Patterson, Claire (LARA) <PattersonC8@michigan.gov>; Rosenzweig, Noah (LARA) <RosenzweigN@michigan.gov>
Subject: RE: Tomorrow

Hi Greg,

Thank you for sharing these documents with us. After reviewing the incubator log, corrective action report, and the updated LOM-7.20 Gene-Up Aspergillus, Viridis North is approved to move forward using the SOP approved as of today to test for Aspergillus. We will also cease placing Viridis North Aspergillus tests on administrative hold. An updated method approval form for Viridis North is attached. While most of the same documentation also applies to Viridis, we are concerned that there is no current incubator log showing into and out of incubator times for Aspergillus test samples at that location. Due to this lack of records, we are withholding approval of the updated LOM-7.20 Gene-Up Aspergillus for Viridis and we will continue placing Viridis Aspergillus tests on administrative hold. The administrative holds for Viridis Aspergillus tests will cease once we have received records confirming that the approved SOP is being followed. If you have questions or concerns, please let me know.

Patrice R. Fields, Ph.D.

Laboratory Scientist Specialist
Scientific & Legal Section, Enforcement Division
Marijuana Regulatory Agency
517-281-3640
FieldsP2@michigan.gov
www.michigan.gov/MRA



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From: Gregoire Michaud <gmichaud@viridisgrp.com>

Sent: Monday, November 15, 2021 11:03 PM

To: Patterson, Claire (LARA) <PattersonC8@michigan.gov>

Cc: Blair, Kevin M. <KBlair@honigman.com>; Todd Welch <twelch@viridisgrp.com>;
drussell@fosterswift.com; Michele Glinn <mglinn@viridisgrp.com>; Michael LaFramboise
<miaframboise@viridisgrp.com>

Subject: RE: Tomorrow

CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

Good evening Claire,

A little miscommunication at our end on who was going to get you these, sorry. Please find attached our corrective action and the two new logs that were put in place as a result of your audit. Bay City implemented the use of the incubator start/end times last Monday with Lansing starting today. Dr. Glinn was out of the lab all last week and the directive to start using it last Monday did not get relayed. We'll monitor it till the end of the month to ensure compliance is consistent at which point we will close out the corrective action. Also attached is our proposed revisions to the SOP that now reflect the use of the log (revisions highlighted in yellow).

Our apologies again for not getting these to you sooner.

Kind regards,

Greg

Complaint, Ex. O



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Public Interest

Moldy, contaminated marijuana may be for sale in Michigan after judge lifts recall

Updated: Dec. 15, 2021, 9:22 a.m. | Published: Dec. 15, 2021, 9:12 a.m.



Jayson Butler of Viridis Laboratories collects cannabis samples, which will later be tested for potency and purity on Tuesday, June 8, 2021. (Mike Mulholland | MLive.com) Mike Mulholland | MLive.com

By [Gus Burns](mailto:gus.burns@mlive.com) | [fburns@mlive.com](mailto:gus.burns@mlive.com)

Contaminated and potentially unsafe marijuana may be for sale in Michigan. And it's no secret.

The Marijuana Regulatory Agency (MRA) on Tuesday, Dec. 14, released for sale an unknown quantity of marijuana that failed testing for unacceptably high levels of mold, yeast or fungi, including possible pathogens, like aspergillus, according to an email that was obtained from the MRA through a Freedom of Information Act request.

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The decision to release the marijuana was in response to a Dec. 3 ruling by Court of Claims Judge Christopher Murray that reversed portions of a massive Nov. 17 recall issued by the MRA.

The MRA placed any marijuana tested by Viridis Laboratories between Aug. 10 and Nov. 16 on hold, until it could be retested. The state's licensing agency deemed test results issued by Viridis, which operates labs in Lansing and Bay City, "unreliable" or "inaccurate." The recall, estimated by Viridis in court filings to be about 64,000 pounds of marijuana flower worth an estimated \$240 million, didn't include inhalable concentrates extracted from marijuana.

Related: 18 health complaints linked to Viridis recall

Once the recall was in place, businesses began scrambling to get product retested and cleared so they could restock their shelves. However, some product failed retesting.

Viridis attorneys then successfully overturned a portion of the recall that pertained to any marijuana products tested by the Bay City Viridis location, whether or not it failed testing in the interim, according to the MRA.

As part of its basis for issuing the recall, the MRA focused on several batches of marijuana suspected of being contaminated with aspergillus, MRA Scientific and Legal Section Manager Claire Patterson said when she testified in the Court of Claims on Dec. 2.

“As it relates to this recall, we had started noticing in ... our statewide monitoring system that packages were failing for aspergillus and then being sent the next day to the (Viridis) laboratories, at which point they were being reported as passing without remediation by the grower,” MRA Scientific and Legal Section Manager Claire Patterson testified on Dec. 2 at a Court of Claims hearing. “Upon receiving that information, we began requesting additional information from the laboratories.”

The MRA randomly selected licensed labs to retest four samples that had previously failed aspergillus testing but were then passed by Viridis, according to Patterson. All of those samples subsequently failed aspergillus testing. While it's known some marijuana retested after the initial recall was found to be contaminated, the MRA hasn't revealed how much failed or was cleared for sale.

“Per the court's order enjoining the MRA from enforcing the recall as to Viridis North, licensees are permitted to sell or transfer those specific products,” the licensing agency said in an email sent to various businesses Tuesday. “This includes product currently at sales locations.”

The MRA has declined to answer questions about the recall, court order or email, citing litigation and an ongoing investigation into Viridis.

“Eventually a Court of Claims judge said you can't recall any of the cannabis from Bay City, but he said it in a way that means they have to release from recall all of the Bay City cannabis, even the cannabis that failed testing,” Rick Thompson, the director for the Michigan chapter of National Organization for the Reform of Marijuana Laws

(NORML) said Tuesday during Jazz Cabbage Cafe, the marijuana-industry-focused podcast and online show he cohosts. “The MRA, in order to comply with the Court of Claims, had to craft a whole workaround, to get around the computer system that’s specifically designed to not let them do what it is they are now doing.”

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Thompson said he never expected the MRA to clear product that has tested positive for biological contaminants.

“I can understand where the court order may have forced their hand, but this is beyond the pale,” he said. “This destroys credibility with the entire system ... Wow. That’s confusing on so many levels.”

Cassin Coleman, director of quality and processing at Carbidex, a group of Michigan marijuana businesses, said as long as retailers are labelling their marijuana properly, customers should be able to see where product was initially tested, if it was retested or if it failed. Retailers must also provide upon request a certificate of compliance that details the testing results for any marijuana products and additional information that isn’t included on labelling.

“People who are concerned because they might be immune compromised, they can ask for evidence,” Coleman said. “They can look at the label and choose not to buy the stuff regardless of whether it’s legal to be sold.”

She said higher than allowed levels of yeast and mold don’t usually pose significant health risks.

"In general, most people are not going to be harmed by mold, unless you have an allergy to mold," Coleman said. "The pathogenic stuff, it's unconscionable that, if we have salmonella on it, that we would sell it in the marketplace."

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"No one should be OK with doing that, and if they were -- I get the court is saying we can, but that's selling adulterated product."

The pathogenic contaminates that Michigan tests for in marijuana includes: salmonella, E. coli and aspergillus.

Prior to the release of marijuana that failed testing before the recall was lifted, the MRA cited at least 18 cases involving "adverse health reactions," up to hospitalization, attributed to recalled marijuana tested by Viridis.

Viridis Labs was founded by three former Michigan State Police Forensic Division employees: Greg Michaud, Todd Welch and Michele Glinn.

"Per the Court's ruling, recalled products tested by the Bay City lab are cleared to go back to market, regardless of the results of the unnecessary retests," said Michaud. "The failed retests have no bearing on the accuracy of our initial laboratory results. Once a sample has cleared point-in-time testing, the associated product goes

through a variety of uncontrolled environments from transportation to processing/packaging, and finally to the provisioning centers where the product is handled by staff and customers. Contamination can and does occur at any part of these handling processes.”

Coleman said contamination after marijuana passes testing “is quite common.”

“It’s a plant,” she said. “Just like you can have your bread go bad or your strawberries go bad, or things like that, it’s got organic matter on it. If it’s contaminated even a little bit in moist conditions, that can lead to growth.”

Coleman said consumer studies of marijuana sold in Colorado and Nevada found 25% of marijuana sold would have failed testing by the time it reached customers.

Nevertheless, Coleman believes it’s the ethical obligation of a business not to sell marijuana they know is contaminated.

The MRA began investigating Viridis in November of 2020, based on concerns over test results that yielded higher than industry average THC potency. High THC content is desirable to customers and increases demand and sales prices for certain strains of marijuana.

The MRA conducted audits at both Viridis labs on Oct. 26 and Oct. 27, during which investigators determined Viridis was producing inaccurate, unreliable results. In order to test for aspergillus, as well as other types of yeast and mold that is potentially harmful, testing labs keep marijuana samples in incubators for certain lengths of times while in a temperature-controlled environment. The MRA found that Viridis wasn’t keeping a log of when samples were placed into or removed from incubators and that, at times, incubation temperatures strayed from the targeted range.

The MRA began looking at Viridis more closely after it noticed inconsistencies related to the aspergillus testing.

Viridis currently has an active license and is permitted by the MRA to conduct all marijuana safety testing. It has a pending administrative complaint filed against the MRA and remains under investigation by the MRA.

Customers who experience any negative reactions to recalled marijuana, or any products sold in the licensed market, are asked to report it to the MRA via email: MRA-Enforcement@michigan.gov, or by phone, 517-284-8599.

More on MLive:

[18 health complaints result from recall](#)

[Viridis fights back in court](#)

[Viridis claims 'bureaucratic' abuse](#)

[Michigan issues \\$200 million marijuana recall](#)

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[How Michigan marijuana became \\$2 billion industry](#)

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**STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS¹
MARIJUANA REGULATORY AGENCY**

In the Matter of

**IRON LABORATORIES, LLC
License No. SC-000003**

**Complaint Nos. 19-2-23,
CMP-19-000097, CMP-19-000124,
CMP-19-000128, CMP-19-000130**

CONSENT ORDER AND STIPULATION

CONSENT ORDER

On August 16, 2019, the Marijuana Regulatory Agency (MRA) issued a formal complaint against the medical marijuana safety compliance facility license (no. SC-000003) of Iron Laboratories, LLC ("Respondent") under the Medical Marijuana Facilities Licensing Act (MMFLA), MCL 333.27101 *et seq.*, and rules promulgated thereunder. The complaint alleged Respondent violated Mich Admin Code, R 333.286(2); R 333.247(1), (9)(d), (14), and (16)(c); 333.248(2)(b); and 333.271(1).

Based on its investigation of the conduct alleged in the complaint, the MRA determined the safety or health of patrons or employees was jeopardized by Respondent's continued operation and that emergency action was required, as authorized under section 407(2) of the MMFLA, MCL 333.27407(2), and section 92(2) of the Administrative Procedures Act, MCL 24.292(2). Therefore, the MRA summarily suspended Respondent's license to operate a medical marijuana facility by order dated August 16, 2019.

¹ Executive Reorganization Order 2019-2 created the Marijuana Regulatory Agency (MRA) as a Type I agency within the Department of Licensing and Regulatory Affairs (LARA). MCL 333.27001(1)(a), (d). The MRA exercises its statutory powers, duties, and functions independent of LARA's direction. MCL 16.103.

The executive director reviewed the stipulation contained in this document and agrees the public interest is best served by resolution of the complaint. Therefore, the executive director finds that the allegations of fact contained in the complaint are true and that Respondent violated Mich Admin Code, R 333.236(2); R 333.247(1), (9)(d), (14), and (16)(c); 333.248(2)(b); and 333.271(1).

Accordingly, for these violations, IT IS ORDERED:

1. The order of summary suspension previously issued on August 16, 2019, is dissolved.
2. Respondent's license is suspended for a minimum of one day commencing on the effective date of this order.
3. Respondent's license automatically shall be reinstated and a renewed license shall be issued when the MRA receives and issues written approval of Respondent's updated standard operating procedures (SOPs) reflecting current, acceptable procedures and practices. This includes, but is not limited to, the following:
 - a. Updated quality assurance/quality control SOPs including, but not limited to, clearly defined procedures for consistently and objectively conducting and documenting repeat testing of samples
 - b. An updated SOP detailing Respondent's microbial testing method to be used beginning on the effective date of this order
4. Commencing on the effective date of this order, Respondent's license is subject to the following restrictions and conditions:
 - a. Corrective Actions: Within 30 days after the effective date of this order, Respondent shall conduct a thorough audit of all internal data and data entered in the statewide monitoring system, correct all data errors and resolve all outstanding samples as directed by the MRA, issue corrected certificates of analysis (COAs) as appropriate, and document all corrective actions on a corrective action and preventative action (CAPA) form. Respondent shall email copies of all CAPA forms and all corrected COAs to MRA-Compliance@michigan.gov.

- b. Accreditation Requirements: Respondent shall satisfy all requirements specified in its August 19, 2019 suspension warning letter from third-party accreditation body Perry Johnson Laboratory Accreditation, Inc. (PJLA). Respondent shall email copies of all documents and communications provided to or received by PJLA within 24 hours of submission to or receipt from PJLA to MRA-Compliance@michigan.gov.
- c. For a period of 180 days from the effective date of this order, Respondent's license is restricted to prohibit Michael Goldman, who was identified as Respondent's chief operating officer at the time of the complaint, from engaging in the following activities on behalf of Respondent:
 - (1) Attending and/or participating in any sampling events
 - (2) Entering or altering any data in the statewide monitoring system
 - (3) Engaging in any financial transactions with customers
- d. For a period ending on the expiration date of Respondent's renewed license, unless a different time period is specified below, Respondent shall comply with the following:
 - (1) Adherence to Established/Approved Procedures: Respondent shall strictly adhere to all of its internal quality control procedures and SOPs as approved by the MRA. Any deviations must be documented and promptly reported to the MRA.
 - (2) Heavy Metals Testing Revalidation: Within 60 days after the date of issuance of this consent order, Respondent shall revalidate and obtain the MRA's written approval of its heavy metals testing method. As part of this revalidation, Respondent shall submit acceptable SOPs that include, at a minimum, updated accuracy, precision, and allowable error. The previous method no longer is approved and the licensee cannot perform testing using the previous method.
 - (3) Entry of Results in Statewide Monitoring System:
 - a) Timely Entry of Results: Respondent shall enter all test results into the statewide monitoring system within 72 hours after a COA is generated.

- b) Pesticide Test Results: Respondent shall enter into the statewide monitoring system actual test results within the reportable range for all pesticide tests, whether the results are uploaded electronically via a comma-separated values (CSV) file or other method.
- (4) COAs: Respondent shall email copies of all COAs that it issues to MRA-Compliance@michigan.gov within 48 hours after the corresponding results are entered in the statewide monitoring system.
- (5) Weekly Report and Data Submission: Respondent shall email copies of the following by 8 a.m. every Monday to MRA-Compliance@michigan.gov.
- a) A sample repeat log documenting every instance of repeat testing during the preceding week, which includes, at a minimum, the sample number, original result, reason for repeat testing, whether the sample was manipulated in any way, and repeat test result selected for entry into the statewide monitoring system
 - b) All raw data uploaded to the statewide monitoring system during the preceding week
 - c) All internal laboratory prep sheets created during the preceding week
 - d) Any CAPA forms created during the preceding week
 - e) Maintenance logs for all laboratory instruments for the preceding week
 - This requirement ends 180 days from the effective date of this order.
- (6) Testing Timeline: Respondent shall complete testing on each sample within 14 days after the sample is received.
- (7) Procedure Revision Approval: If Respondent revises any procedures or documents that otherwise require MRA approval for accreditation or other purposes, such revisions also must be approved in writing by the MRA.

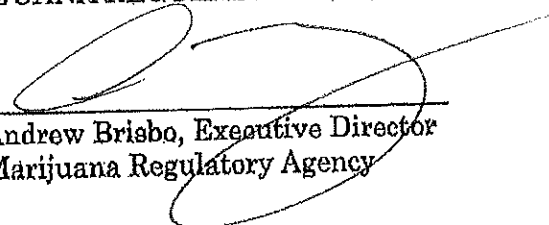
5. Respondent must pay a fine in the amount of one hundred thousand and 00/100 dollars (\$100,000.00). This fine shall be paid within 90 days of the effective date of this order by check or money order made payable to the State of Michigan with complaint number "19-2-23 *et seq.*" clearly displayed on the check or money order. Respondent shall mail the fine to Department of Licensing and Regulatory Affairs, Marijuana Regulatory Agency, P.O. Box. 30205, Lansing, Michigan 48909, or Respondent may pay online through the Accela Citizen Access Portal (<https://aca3.accela.com/MIMM>).
6. If Respondent fails to timely pay the fine, Respondent's license shall be suspended until payment is received.
7. Unless otherwise specified in this order, Respondent shall direct any communications to the MRA that are required by the terms of this order to MRA-Compliance@michigan.gov.
8. Respondent shall be responsible for all costs and expenses incurred in complying with the terms and conditions of this consent order.
9. Respondent shall be responsible for the timely compliance with all terms of this consent order, including the timely filing of any documentation. Respondent's failure to comply within the time limitations provided will constitute a violation of this order. The MRA may, in its discretion, grant a written extension of any timeline set forth in this consent order on a case-by-case basis and in response to a written request from Respondent.
10. If Respondent violates any term or condition set forth in this order, Respondent will be subject to fines and/or other sanctions under section 407(1) of the MMFLA, MCL 333.27407(1), and Mich Admin Code, R 333.219.

This consent order is intended to encompass and resolve the specific conduct and violations alleged in the August 16, 2019 formal complaint; the specific conduct and violations alleged in investigation numbers 19-2-33, 19-2-35, 19-2-36, 19-2-41, and 19-2-55; and any additional occurrences of the same conduct and violations that pre-date the formal complaint.

This order shall be effective on the date signed by the MRA's executive director or his designee, as set forth below.

MARIJUANA REGULATORY AGENCY

Signed on: 10/9/2019

By: 
Andrew Brisbo, Executive Director
Marijuana Regulatory Agency

STIPULATION

The parties stipulate to the following:

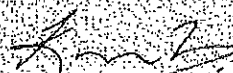
1. Respondent does not contest the allegations of fact and law in the complaint. By pleading no contest, Respondent does not admit the truth of the allegations but agrees that the MRA's executive director may enter an order treating the allegations as true for purposes of resolving the complaint.
2. Respondent understands and intends that by signing this stipulation, Respondent is waiving the right under the MMFLA, rules promulgated thereunder, and the Administrative Procedures Act of 1969, MCL 24.201 *et seq.*, to require the MRA to prove the charges set forth in the complaint by presentation of evidence and legal authority, and to present a defense to the charges.
3. The parties considered the following in reaching this agreement:
 - a. In a compliance conference conducted on September 9, 2019, and follow-up communications, Respondent's representatives explained that Respondent has taken steps to improve its business practices and prevent recurrences, including better educating its staff and revising its testing and reporting procedures.


- b. Respondent was formally removed from the A2LA accreditation program on September 19, 2019, after requesting to forego its assessment plan with the accrediting body. Respondent understands that it no longer is approved by the MRA to use any of the testing methods previously accredited by A2LA.
- c. Respondent understands that it may be subject to more frequent inspections moving forward to ensure compliance with the MMFLA and associated rules.
- d. Respondent was cooperative and wishes to resolve the allegations without the need for and expense of an administrative hearing.

4. The MRA's enforcement division director or her designee must approve this proposed agreement before it is forwarded to the MRA's executive director or his designee for review and issuance of the above consent order. The parties reserve the right to proceed to an administrative hearing without prejudice to either party, should the MRA's enforcement division director, executive director, or their designees reject the proposed consent order.


By signing this stipulation, the parties confirm that they have read, understand, and agree with the terms of the consent order.


AGREED TO BY:


 Kavita Kale
 Enforcement Division Director
 Marijuana Regulatory Agency
 Dated: 10/9/19


 Erika N. Marzorati (P78100)
 Assistant Attorney General
 Attorney for Complainant
 Dated: 10-8-19

AGREED TO BY:


 Howard Lutz, Authorized Officer
 On behalf of Respondent
 Iron Laboratories, LLC
 Dated: 10-7-19


 Seth P. Tompkins (P63249)
 Attorney for Respondent
 Dated: 10-7-19

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS¹
MARIJUANA REGULATORY AGENCY

In the Matter of

IRON LABORATORIES, LLC
License No. SC-000003

Complaint Nos. 19-2-23,
CMP-19-000097, CMP-19-000124,
CMP-19-000128, CMP-19-000130

FORMAL COMPLAINT

Attorney General Dana Nessel, through Assistant Attorney General Erika N. Marzorati, on behalf of the Marijuana Regulatory Agency (Complainant), files this formal complaint against Iron Laboratories, LLC (Respondent), alleging upon information and belief as follows:

1. The Marijuana Regulatory Agency (MRA) is authorized under the Medical Marihuana Facilities Licensing Act (MMFLA), MCL 333.27101 *et seq.*, and Executive Reorganization Order No. 2019-2, MCL 333.27001, to investigate alleged violations of the MMFLA and rules promulgated thereunder, take disciplinary action to prevent such violations, and impose fines and other sanctions against applicants and licensees that violate the MMFLA or rules.

2. Section 407(2) of the MMFLA provides for the summary suspension of a license. The section reads, in pertinent part:

The [MRA] may suspend a license without notice or hearing upon a determination that the safety or health of patrons or employees is

¹ Executive Reorganization Order 2019-2 transferred all authority, power, duties, functions, and responsibilities of the Department of Licensing and Regulatory Affairs (LARA) under the state's marijuana statutes to the Marijuana Regulatory Agency (MRA), a Type I agency created within LARA. MCL 333.27001(1)(a), (d). The MRA exercises its statutory powers, duties, and functions independent of LARA's direction. MCL 16.103.

jeopardized by continuing a marihuana facility's operation. If the [MRA] suspends a license under this subsection without notice or hearing, a prompt postsuspension hearing must be held to determine if the suspension should remain in effect.

3. Section 402(12) of the MMFLA provides that the expiration of a license does not terminate the MRA's authority to impose sanctions on the licensee.

FACTUAL ALLEGATIONS AND INTENDED ACTION OF THE MRA

4. Respondent holds a state operating license under the MMFLA to operate a safety compliance facility in the state of Michigan. Respondent's license expired on August 9, 2019. Respondent has a pending application for license renewal.

5. Respondent operated a safety compliance facility in Walled Lake, Michigan, at all times relevant to this complaint.

6. Following an investigation, the MRA determined that Respondent violated the MMFLA and/or rules promulgated thereunder as set forth below:

a. Complaint No. CMP-19-000124

- i. On or about July 23, 2019, Respondent performed a compliance test on test package #1A4050100000385000000477.
- ii. Respondent detected 0.439 ppm of Myclobutanil in the sample. This result is more than twice the state action limit of 0.2 ppm (parts per million).
- iii. Myclobutanil is a highly toxic pesticide that is harmful if swallowed or absorbed through the skin and may release toxic fumes if burned. For this reason, it is listed as a banned chemical active ingredient in Michigan.
- iv. Respondent reported the test result for Myclobutanil as 0.439 ppm, a failing result, on the certificate of analysis provided to the client that provided the sample.

- v. Respondent failed to enter the failing test result for Myclobutanil into METRC, the statewide monitoring system. Instead, Respondent reported in METRC that the sample passed with 0 ppm detected for all pesticides.
 - vi. Respondent failed to report the failing test result to the MRA when it transmitted the results to the client.
 - vii. Based on the above, Respondent failed to enter the results into the statewide monitoring system and file with the MRA an electronic copy of a test result for a batch that did not pass the required tests when it transmitted those results to the facility that provided the sample, in violation of Mich Admin Code, R 333.247(14).
 - viii. Based on the above, Respondent failed to comply with and/or falsified records related to Mich Admin Code, R 333.247. Per Mich Admin Code, R 333.247(15), this requires the MRA to take immediate disciplinary action.
 - ix. Based on the above, Respondent pre-tested samples, in violation of Mich Admin Code, R 333.247(16)(c).
- b. Complaint No. CMP-19-000128
- i. On or about July 12, 2019, Respondent performed two retests each on Platinum Punch flower (test package #1A4050100000900000005804) and Super Glue flower (test package #1A4050100000900000005853) that previously failed testing for total yeast and mold at a level of 21,000 cfu (colony forming units) at a different safety compliance facility.
 - ii. Respondent detected and reported in METRC passing results of 0 cfu/gram for both retests on both samples. This result is scientifically implausible, based on the technology Respondent used to conduct the tests and the fact the client that supplied the flower performed no remediation and did not alter the samples prior to their transfer to Respondent.
 - iii. The same samples were sent to a third safety compliance facility for auditing. The third facility's audit test results detected total yeasts and molds at concentrations exceeding zero, with one result exceeding the state action limit.

- iv. Based on the above, Respondent failed to use analytical testing methodologies for required safety tests that may be monitored on an ongoing basis by the MRA or a third party, including either the current version of the *Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control* monograph published by the American Herbal Pharmacopoeia or an alternative testing methodology approved by the MRA and validated by an independent third party that the methodology followed produces scientifically accurate results for each safety test it conducts, in violation of Mich Admin Code, R 333.247(1).
 - v. Based on the above, Respondent failed to comply with and/or falsified records related to Mich Admin Code, R 333.247. Per Mich Admin Code, R 333.247(15), this requires the MRA to take immediate disciplinary action.
- c. Complaint No. CMP-19-000097
- i. On July 19, 2019, as part of an MRA audit, Respondent conducted a reanalysis test of two infused edible product samples (test packages #1A4050100000900000010101 and 10102) that previously were tested at a different safety compliance facility.
 - ii. Respondent reported in METRC total THC potency (delta-9 tetrahydrocannabinol concentration) results for both samples as “mg/g” (milligrams of THC per gram of product).
 - iii. Respondent’s reported results failed to account for the total weight of the product and the number of servings in the product.
 - iv. On the certificate of analysis provided to the client that provided the samples, Respondent reported the THC potency result as “fail[ed] for over maximum level of active Delta 9 THC allowed per container.”
 - v. Respondent failed to enter the failing THC potency test result into METRC. Instead, Respondent incorrectly reported in METRC that the sample passed.
 - vi. Respondent failed to report the failing test result to the MRA when it transmitted the results to the client.

- vii. Based on the above, Respondent failed to enter the results into the statewide monitoring system and file with the MRA an electronic copy of a test result for a batch that did not pass the required tests when it transmitted those results to the facility that provided the sample, in violation of Mich Admin Code, R 333.247(14).
 - viii. Based on the above, Respondent failed to comply with and/or falsified records related to Mich Admin Code, R 333.247. Per Mich Admin Code, R 333.247(15), this requires the MRA to take immediate disciplinary action.
 - ix. Based on the above, Respondent pre-tested samples, in violation of Mich Admin Code, R 333.247(16)(c).
- d. Complaint No. CMP-19-000130
- i. On or about June 29, 2019, Respondent accepted products for testing from a licensed grower under manifest numbers 0000055601 and 0000062555. The manifests included a total of 17 test packages with the following numbers: 1A4050100001D4E0000000008, 0009, 0010, 0011, 0012, 0013, 0014, 0025, 0026, 0027, 0028, 0029, 0030, 0031, 0032, 0033, and 0034.
 - ii. On certificates of analysis provided to the client that provided the samples, Respondent reported that seven of the samples failed for pesticide results above the state action limit.
 - iii. Respondent entered the results into METRC for all of the samples that passed testing. However, Respondent failed to enter any of the seven failing results in the statewide monitoring system.
 - iv. Respondent failed to report the failing test results to the MRA when it transmitted the results to the client.
 - v. Based on the above, Respondent failed to enter the results into the statewide monitoring system and file with the MRA an electronic copy of a test result for a batch that did not pass the required tests when it transmitted those results to the facility that provided the sample, in violation of Mich Admin Code, R 333.247(14).

- vi. Based on the above, Respondent failed to comply with and/or falsified records related to Mich Admin Code, R 333.247. Per Mich Admin Code, R 333.247(15), this requires the MRA to take immediate disciplinary action.
 - vii. Based on the above, Respondent pre-tested samples, in violation of Mich Admin Code, R 333.247(16)(c).
- e. Complaint No. CMP-19-2-23
- i. During a sampling event on March 15, 2019, Respondent's chief operating officer, M.G., requested that the client facility not select the "research and development" test in METRC and indicated he would notify the client of any failed results to provide the client an opportunity to remediate the products without "lock[ing] the package up" in METRC.
 - ii. On March 15, 2019, Respondent collected eight packages from a client for product testing. Respondent weighed only one of the packages, but recorded a weight for each of the eight on the chain of custody form.
 - iii. Three of the samples Respondent collected on March 15, 2019 (test packages #1A4050100000C81000000785, 0792, and 0788) were less than 0.5% of the weight of the batch.
 - iv. On March 15, 2019, Respondent failed to tag or label marijuana product with tracking identification numbers (sample tags).
 - v. On April 1, 2019, Respondent collected four samples (test packages #1A4040100000191000000849, 901, 912, and 998) that were less than 0.5% of the weight of the batch.
 - vi. On or about April 5, 2019, a lab report revealed that Respondent used method FE 62 to test sample package #1A4040100000191000000953. This method is not included in the *Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control* monograph published by the American Herbal Pharmacopoeia; was not approved by the MRA; and was not validated by a third-party accreditor to ensure scientifically accurate results.

- vii. During an on-site inspection on April 5, 2019, Respondent was unable to provide its field kit for inspection and was unable to verify that its field kit's analytical balance (scale) was properly calibrated.
- viii. Following the April 5, 2019 inspection, Respondent provided a calibration certificate that had no serial number listed and was unable to be traced.
- ix. Following the April 5, 2019 inspection, Respondent provided the MRA with an internal corrective action report that acknowledged Respondent's scales had an expired calibration that does not conform to the ISO/IEC 17025:2005 or 17025: 2017 standards.
- x. During an on-site visit on April 15, 2019, MRA staff discovered five packages of marijuana product that had no METRC tracking label affixed to the package and no tracking information.
- xi. Based on the above, Respondent possessed marijuana product without a batch number or identification tag or label, in violation of Mich Admin Code, R 333.236(2).
- xii. Based on the above, Respondent failed to use analytical testing methodologies for required safety tests that may be monitored on an ongoing basis by the MRA or a third party, including either the current version of the *Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control* monograph published by the American Herbal Pharmacopoeia or an alternative testing methodology approved by the MRA and validated by an independent third party that the methodology followed produces scientifically accurate results for each safety test it conducts, in violation of Mich Admin Code, R 333.247(1).
- xiii. Based on the above, Respondent failed to maintain a quality control and quality assurance program that conforms to ISO/IEC 17025:2005 or 17025:2017 standards, in violation of Mich Admin Code, R 333.247(9)(d).
- xiv. Based on the above, Respondent failed to comply with and/or falsified records related to Mich Admin Code, R 333.247. Per Mich Admin Code, R 333.247(15), this requires the MRA to take immediate disciplinary action.

- xv. Based on the above, Respondent pre-tested samples, in violation of Mich Admin Code, R 333.247(16)(c).
- xvi. Based on the above, Respondent failed to collect a sample size not less than 0.5% of the weight of the batch, in violation of Mich Admin Code, R 333.248(2)(b).
- xvii. Based on the above, Respondent failed to ensure marijuana products transferred between facilities had tracking identification numbers assigned by the statewide monitoring system affixed, tagged, or labeled and recorded, in violation of Mich Admin Code, R 333.271(1).

7. Based on the above, Respondent lacks integrity, moral character, and responsibility or means to operate or maintain a marijuana facility. MCL 333.27402(3)(a).

8. Based on the above, Respondent has a history of noncompliance with regulatory requirements in this state. MCL 333.27402(3)(g).

9. Based on the above, Respondent fails to meet other standards in rules applicable to its license category. MCL 333.27402(3)(i).

THEREFORE, based on the above, the MRA gives notice of its intent to impose fines and/or other sanctions against Respondent's license, which may include the suspension, revocation, restriction, and/or refusal to renew Respondent's license.

Under MCL 333.27407(4) and Mich Admin Code, R 333.29494(2), any party aggrieved by an action of the MRA suspending, revoking, restricting, or refusing to renew a license, or imposing a fine, shall be given a hearing upon request. A request for a hearing must be submitted to the MRA in writing within 21 days after service of this complaint. Notice served by certified mail is considered complete on the business day following the date of the mailing.

Respondent also has the right to request a compliance conference under Mich Admin Code, R 333.294(1). A compliance conference is an informal meeting at which Respondent has the opportunity to discuss the allegations in this complaint and demonstrate compliance with all lawful requirements for retention of the license under the MMFLA and/or rules. A compliance conference request must be submitted to the MRA in writing.

Hearing and compliance conference requests must be submitted in writing by one of the following methods, with a copy to the undersigned assistant attorney general.

By Mail: Department of Licensing & Regulatory Affairs
Marijuana Regulatory Agency
P.O. Box. 30205
Lansing, Michigan 48909

In Person: Department of Licensing & Regulatory Affairs
Marijuana Regulatory Agency
2407 North Grand River
Lansing, Michigan 48906

If Respondent fails to timely respond to this formal complaint, a contested case hearing will be scheduled to resolve this matter.

Questions about this complaint should be directed to the undersigned
assistant attorney general at 517-335-7569.

Respectfully Submitted,

DANA NESSEL
Attorney General



Michelle M. Brya (P66861)
Joshua O. Booth (P53847)
Erika N. Marzorati (P78100)
Assistant Attorneys General
Licensing and Regulation Division
P.O. Box 30758
Lansing, Michigan 48909
(517) 335-7569

Dated: August 16, 2019

LF: 2019-0262219-A / Iron Laboratories, LLC / Formal Complaint - 2019-08-16



PUBLIC HEALTH AND SAFETY BULLETIN

August 30, 2019

Notification of Medical Marijuana Product Recalls

The Marijuana Regulatory Agency (MRA) recalled four medical marijuana products today as a result of the ongoing investigation into the testing and reporting practices of Iron Laboratories.

All affected medical marijuana is required to have a label affixed to the container that indicates the METRC number assigned to the marijuana product. Patients and caregivers should look for the production batch number associated with the product name or the individual package number which can be found under the name of the provisioning center at which the product was sold.

Possible medical issues or symptoms could include coughing, wheezing, decreased pulmonary function, nausea, vomiting, abnormal heart rhythm, and damage to blood vessels. This recall affects the following products sold at numerous provisioning centers throughout the state of Michigan:

Production batch: 1A405010000076F000001671
Product Name: RSO 1G. SYRINGE-MONSTER X-
Failed testing on 5/2/19 for Chemical Residue - Bifenazate

MPM-R FLINT LLC (PC-000052)
310 S. Averill Ave
Flint MI 48506
1A405010000076F000003347

The Remeddi Station (PC-000267)
302 E. Huron Avenue
Vassar MI 48768
1A405010000076F000003366

Pharmaco, Inc. (PC-000249)
3650 Patterson RD
Bay City MI 48706
1A405010000076F000003365

This advisory bulletin does not constitute legal advice and is subject to change. Licensees are encouraged to seek legal counsel to ensure their operations comply with the Medical Marijuana Facilities Licensing Act and associated Administrative Rules.



PUBLIC HEALTH AND SAFETY BULLETIN

August 30, 2019

Pharmaco, Inc. (PC-000232)
160 E. Columbia Ave.
Battle Creek MI 49015
1A405010000076F000003364

Pharmaco, Inc. (PC-000226)
20477 Schaefer HWY
Detroit MI 48235
1A405010000076F000003363

Pharmaco, Inc. (PC-000205)
20561 Dwyer ST
Detroit MI 48234
1A405010000076F000003367

Production batch: 1A4050100002330000000011
Product Name: Glue-Buds
Failed testing on 6/14/19 for Heavy Metal - Cadmium

Pharmaco, Inc. (PC-000226)
20477 Schaefer HWY
Detroit MI 48235
1A4050100002330000000049

Pharmaco, Inc. (PC-000249)
3650 Patterson RD
Bay City MI 48706
1A4050100002330000000060

Production batch: 1A4050100000900000007057
Product Name: 1g - Platinum Vapes - Diamond OG Cartridge
Failed testing on 6/25/19 for Heavy Metal - Total Chromium

Green Door Alternative (PC-000233)
7304 Michigan AVE
Detroit MI 48210
1A4050100000900000008308

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PUBLIC HEALTH AND SAFETY BULLETIN

August 30, 2019

Green Skies-Hoover LLC (PC-000099)
20580 Hoover
Detroit MI 48205
1A4050100000900000008322

Pharmaco, Inc. (PC-000249)
3650 Patterson RD
Bay City MI 48706
1A4050100000900000008330

Pharmaco, Inc. (PC-000259)
18334 W Warren Avenue
Detroit MI 48228
1A4050100000900000008333

Pharmaco, Inc. (PC-000205)
20561 Dwyer ST
Detroit MI 48234
1A4050100000900000008337

Bigfoot Wellness (PC-000092)
4045 Court ST
Burton MI 48059
1A4050100000900000008345

Thrive Provisioning Center (PC-000190)
6007 Ann Arbor RD
Jackson MI 49201
1A4050100000900000008373

664 Vassar, LLC (PC-000035)
664 State RD
Vassar MI 48768
1A4050100000900000008467

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PUBLIC HEALTH AND SAFETY BULLETIN

August 30, 2019

Production batch: 1A4050100000900000010327
Product Name: 1g Savage Signature OG Budder - Concentrate
Failed testing on 7/17/19 for Heavy Metal- Arsenic

Meds Cafe (PC-000238)
2352 US-23 South
Rogers City MI 49779
1A4050100000900000016461

Green Skies-Healing Tree, LLC (PC-000100)
15308 8 Mile RD
Detroit MI 48205
1A4050100000900000016183

Green Skies-Hoover LLC (PC-000099)
20580 Hoover
Detroit MI 48205
1A4050100000900000016646

Green Skies-Far West, LLC (PC-000098)
21221 8 Mile RD
Detroit MI 48219
1A4050100000900000016200

Wayne PRV, Inc. (PC-000068)
5405 Cogswell RD
Wayne MI 48184
1A4050100000900000016155

Thrive Provisioning Center (PC-000190)
6007 Ann Arbor RD
Jackson MI 49201
1A4050100000900000016418

Choice Labs (PC-000118)
6031 Ann Arbor RD
Jackson MI 49201
1A4050100000900000015215
1A4050100000900000017465

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PUBLIC HEALTH AND SAFETY BULLETIN

August 30, 2019

KZoo Retailers LLC (PC-000025)
521 E. Mosel Ave
Kalamazoo MI 49004
1A4050100000900000015678
1A4050100000900000015684

Royal Highness (PC-000242)
11392 West Jefferson
River Rouge MI 48218
1A4050100000900000015956
1A4050100000900000017632

Flower Bowl (PC-000229)
28661 Michigan AVE
Inkster MI 48141
1A4050100000900000017000

Green Wellness Ventures, LLC (PC-000248)
101 N Front St, Suite A
Chesaning MI 48616
1A4050100000900000017460

Skozee, LLC (PC-000093)
4184 Pier North BLVD, Suite A
Flint MI 48504
1A4050100000900000017476

Gage Cannabis Co. (PC-000290)
1551 Academy Street
Ferndale MI 48220
1A4050100000900000017299
1A4050100000900000018088
1A4050100000900000019074

Kenzy Consulting Inc (PC-000154)
539 South Huron
Ypsilanti MI 48197
1A4050100000900000018456

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PUBLIC HEALTH AND SAFETY BULLETIN

August 30, 2019

Clark Street Investment Group Inc (PC-000254)
6640 E 8 Mile RD
Detroit MI 48234
1A4050100000900000017939

Patients or caregivers who have these affected medical marijuana products in their possession should destroy them or return them to the provisioning center from which they were purchased.

The MRA has not been made aware of any adverse product reactions in conjunction with these products; however, the MRA is continuing to investigate this matter and will issue further bulletins if appropriate. Patients and caregivers are requested to report any adverse product reactions to the MRA via email: MRA-Enforcement@michigan.gov or via phone: 517-284-8597.

Patients and caregivers who would like to have products tested – at their own expense – can take them to a licensed safety compliance facility. Questions can be sent to Operations Support Section via email at MRA-Compliance@michigan.gov.

For more information about the Marijuana Regulatory Agency, please visit
www.michigan.gov/MRA.

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GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

ORLENE HAWKS
DIRECTOR

January 31, 2020

Compliance Action – Citation

Palmatier Enterprises, Inc.,
Assumed Name The Spott

ERG No.: 000175
License No.: SC-000002
CMP No.: 19-000083 & 19-000735
ENF No.: 19-00049 & 19-00062

Following an investigation, the Marijuana Regulatory Agency (MRA) determined that Palmatier Enterprises, Inc., Assumed Name The Spott ("Respondent"), license no. SC-000002, violated the Medical Marijuana Facilities Licensing Act (MMFLA), and/or administrative rules promulgated thereunder as follows:

1. ENF No. 19-00049

- a. On July 12, 2019, a licensed grower ("Complainant") submitted a complaint to the MRA about the validity of microbial results received from Respondent on marijuana product (flower). Complainant packaged the same flower into two packages, tag nos. 1A4050100001D4D000000096 (package tag #0096) and 1A4050100001D4D000000093 (package tag #0093). Package tag #0096's initial results indicated BTGN at 2800 CFU/g, TC at 2200 CFU/g, and TYM at 14250 CFU/g; these results exceed the MRA's published action limit, and thus are failing results. Package tag #0093's initial results indicated BTGN at ND (not detected), TC at ND, and TYM at 2300 CFU/g; these results did not exceed the MRA's published action limit, and thus are passing results. The failures from package tag #0096 contained bacteria failures (microbes); package tag #0093's results did not detect bacteria. Although it is possible to have a failing and passing result on the same flower, typically, detection from the additional microbes would be seen. Therefore, the MRA questioned the validity of these results. At the MRA's request, Respondent analyzed its field duplicates for both samples. Package tag #0096's field duplicate analysis results indicated BTGN at ND, TC at ND, and TYM at 650 CFU/g; and, package tag #0093's field duplicate analysis results indicated BTGN at ND, TC at ND, and TYM at 1050 CFU/g. The original results and the field duplicate results did not correlate. Therefore, Respondent failed to use analytical testing methodologies that produced scientifically accurate results.

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DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

ORLENE HAWKS
DIRECTOR

- b. Based on the above, Respondent's analytical testing methodologies for the required safety tests do not produce scientifically accurate results for each test it conducts in violation of Mich Admin Code, R 333.247(1)(b).
2. ENF No. 19-00062
- a. On August 1, 2019, Respondent retested MKX Blue Raz Cart, MKX Forbidden Fruit Cart, and MKX Strawberry Lemonade Cart which are marihuana products intended for inhalation; this marihuana product is where the marihuana concentrate has been placed into the inhalation device. This is the form that it is in when available for sale, i.e., a marihuana product that is in a final package.
- b. MKX Blue Raz Cart, METRC source tag number 1A405010000170D000000068 (source tag #0068) had initial compliance testing by another licensee on July 16, 2019; the sample tag number for the initial compliance testing was 1A405010000170D000000111; failing results were uploaded to METRC on July 24, 2019.
- c. On August 1, 2019, Respondent sampled source tag #0068; the sample tag numbers were 1A405010000170D000000414 and 1A405010000170D000000415. On August 8, 2019, Respondent uploaded failing test results in METRC.
- d. MKX Forbidden Fruit, METRC source tag number 1A405010000170D000000070 (source tag #0070); and MKX Strawberry Lemonade Cart, METRC source tag A405010000170D000000077 (source tag #0077) had initial compliance testing by another licensee on July 25, 2019.
- e. On August 1, 2019, Respondent sampled source tag #0070; the sample tag numbers were 1A405010000170D000000416 and 1A405010000170D000000417. On August 8, 2019, Respondent uploaded failing test results in METRC.
- f. On August 1, 2019, Respondent sampled source tag #0077 were sampled for retesting; the sample tag numbers were 1A405010000170D000000418 and 1A405010000170D000000419. On August 8, 2019, Respondent uploaded failing test results in METRC.
- g. Based on the above actions after August 1, 2019, Respondent retested marihuana product that was in its final package, in violation of Mich Admin Code, R 333.246(3)(a).

Mich Admin Code, R 333.219 provides that a licensee found in violation of the MMFLA and/or administrative rules may be subject to sanctions, including fines. For the above violations, the MRA intends to impose a fine of \$4,000.00.

If you agree to resolve this citation as set forth in the citation agreement below, you must sign and return the attached citation agreement within 30 days after receipt of the citation. The fine must be paid within 30 days after you receive the citation agreement signed by the enforcement director. Return the signed agreement and submit payment by:

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DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

ORLENE HAWKS
DIRECTOR

Mailing to:

Department of Licensing & Regulatory Affairs
Marijuana Regulatory Agency
P.O. Box. 30205
Lansing, Michigan 48909

Appearing in Person:

Department of Licensing & Regulatory Affairs
Marijuana Regulatory Agency
2407 North Grand River
Lansing, Michigan 48906

Online:

You may use the online Accela Citizen Access Portal (<https://aca3.accela.com/MIMM>) to upload the signed citation agreement and remit payment.

Checks must be made payable to the State of Michigan and include the above enforcement (ENF) number on the memorandum line.

A citation and fully executed citation agreement may be disclosed to the public. You may submit a one-page explanation that will be placed in your license record and may be disclosed each time the citation and/or citation agreement is disclosed to the public. ***If no further disciplinary actions are imposed on your license within five calendar years after the citation is issued, the MRA will remove this citation from this license record.***

If you fail to sign the citation agreement and timely pay the fine, the allegations in this citation will be incorporated into a formal complaint and will result in further administrative proceedings.

Continued or repeated non-compliance or repeated violations may result in further action, including the imposition of fines and/or other sanctions against your license.

Any questions about this citation should be directed to the MRA's legal section at (517) 284-8599 or MRA-LegalHearings@michigan.gov.

Dated: 31 Jan 2020

MARIJUANA REGULATORY AGENCY

By: [Signature]
Kavita Kale, Enforcement Division Director

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GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

ORLENE HAWKS
DIRECTOR

CITATION AGREEMENT ("Agreement")

By signing below, Respondent and the Marijuana Regulatory Agency (MRA) agree that:

1. This agreement is not valid or enforceable until executed by both the enforcement director and Respondent.
2. This agreement constitutes a full and final resolution of this citation. However, this agreement does not preclude the MRA from opening a separate investigation and pursuing appropriate disciplinary action based on information that was knowingly or unknowingly withheld by Respondent or otherwise not discovered during the initial investigation.
3. Respondent and the MRA agree that each has the authority to settle the citation in accordance with the terms of this agreement.
4. The interests of the public, the MRA, and Respondent are best served by entering into this agreement without further proceedings.
5. Respondent agrees to timely pay the fine set forth in the citation.
6. Respondent does not admit the truth of the allegations in the citation but agrees that the MRA may treat the allegations as true for purposes of resolving the citation.
7. The MRA reserves the right to consider this agreement in the context of subsequent disciplinary proceedings and license application or renewal decisions.

Respondent:
Palmatier Enterprises, Inc.,
Assumed Name The Spott
License No. SC-000002

Marijuana Regulatory Agency

By: Linda Palmatier

Title: President

Date: 2/27/20

By: Kavita Kale

Enforcement Division Director

Date: 03/02/2020

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ENF No. 19-00049

Respondent Explanation

1. Respondent takes issue with the following MRA assertion:

"Although it is possible to have a failing and passing result on the same flower, typically, detection from the additional microbes would be seen."

As a matter of scientific fact, microbiological contamination within a large collection of source flower material is typically very localized to one or more distinct buds, is not homogenous within the larger collection, and detection is not necessarily probable in the absence of complete homogenization of the material.

2. Respondent takes issue with the broad MRA conclusion that:

"Respondent failed to use analytical testing methodologies that produced scientifically accurate results."

While respondent welcomes an opportunity to improve testing methodology, the methodologies employed for microbiological testing are sound, based upon *Cannabis Inflorescence: Standard of Identity, Analysis, and Quality Control*, and AOAC (2019) reference methods, as required by current regulations. Respondent passed quantitative microbial proficiency tests (CM-0419) for 2019 on 05/16/2019 and for 2018 (CM-0418) on 05/21/2018.

As a result of this incident, as of 07/23/2019, respondent formally implemented complete homogenization of the entirety of sampled material prior to withdrawing sub-samples for microbiological tests to provide additional assurance that microbiological test results are consistent. (Ref: NCR-2019-019 and CAR-2019-019.)

ENF No. 19-00062

Respondent Explanation

Respondent takes issue with MRA enforcement action on this issue. At the time referenced in the citation, formal regulatory definition of "final packaging" was absent. To date, a clear definition remains absent from approved regulations, rules, and associated guidelines.

1. The industry-accepted definition of "Primary Packaging" is the package component that is in direct contact with the product.
2. The industry-accepted definition of "secondary packaging" are the package components that are presented to the customer at the point of sale that are not in direct contact with the product.

In the case of a vaporization cartridge, the vaporization device that contains the cannabis product is "primary packaging." The vaporization device is placed into secondary packaging prior to being made available for purchase.

Language in Draft Rule for Marihuana Sampling and Testing (issued for public comment on or about 1/13/2020) R 420.301 Definitions, item (h) states:

"Final package" means the form a marihuana product is in when it is available for sale by a marihuana sales location."

Respondent asserts that the vaporization cartridges that are the subject of this enforcement action were in their Primary Package, but not Final Package as defined in the Draft Rule and that this regulatory action is not warranted.